

**The Relative Efficacy of Homoeopathic Simillimum Treatment as Compared to Psychological Counseling (Cognitive Therapy and Behavioral Therapy) in the Management of Generalized Anxiety Disorder.**

**By**

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Mini dissertation submitted in partial compliance with the requirements for the Master's Degree in Technology: Homoeopathy, in the Faculty of Health Sciences at the Durban Institute of Technology.

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# DEDICATION

This one is dedicated to my parents (Mr. & Mrs. Mnyandu). I wouldn't be where I am today if it weren't for you. I greatly humble myself and am very much grateful to you for making my dream possible to study Homoeopathy.

I thank you for your undying love, sacrifices, guidance and support you have given me all these years. I am proud to dedicate this to you. You have reached beyond yourselves by giving effortlessly and wholeheartedly all that you could. I LOVE YOU. GOD BLESS YOU.

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To those with no concern for the Way; those temporarily lost on the Way;  
Those diligently seeking the Way; those who know, but are unable to follow the Way;  
Those who simply live the Way...For all of us are one!!!

**With love: *Jabulile Ngobese***

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*You can't live a perfect day without doing something for someone who will never be able to repay you.*

*John Wooden*

TRUE HEALTH IS NOT JUST THE ABSENCE OF SYMPTOMS; IT IS CHARACTERIZED BY FEELING PHYSICALLY WELL, BEING SELF-RELIANT, HAVING THE ABILITY TO ADJUST TO CHANGE, AND HAVING A SENSE OF RESPONSIBILITY FOR ONESELF. THIS ENTAILS DEVELOPING INSIGHT INTO ONE'S OWN FEELINGS AND ACTIONS, AND CULTIVATING A DEGREE OF SELF-WORTH THAT CAN STAND ON IT'S OWN WITHOUT THE GOOD OPINION OF OTHERS.

*DRUGS ARE NOT ALWAYS NECESSARY, BUT BELIEF IN RECOVERY ALWAYS IS.*

## ABSTRACT

This double-blind placebo-controlled study investigated the relative efficacy of Homoeopathic similimum treatment as compared to psychological counselling (Cognitive therapy combined with Behavioural therapy), in the management of Generalized Anxiety Disorder (GAD).

Anxiety is an unpleasant emotional state that has less than a clear source. It is often accompanied by physiological and behavioural changes similar to those caused by fear, or a response to stress, such as the break up of an important relationship or exposure to a life threatening disaster (Berkow, 1997: 395).

GAD is excessive anxiety and worry (apprehensive expectation), occurring more days than not for a period of at least 6 months, in response to a number of events or activities such as work or social performance (DSM-IV, 1994: 433).

This clinical trial consisted of 3 groups; Group 1 (Homoeopathic similimum treatment only); Group 2 (Psychological Counselling and placebo powders) and Group 3 (Placebo powders only).

Convenience sampling was utilized, whereby 41 participants were selected for the study on the basis of inclusion and exclusion criteria according to the DSM-IV (1994) diagnostic criteria for 300.02.

A process of randomization was used to allocate patients to the three groups. A total of 34 participants completed the study.

In the Simillimum group 11 participants completed the 4-week trial, which included 3 homoeopathic consultations (and 6 active treatment powders). In the Psychological Counselling group 10 participants completed the 4-week trial, which included 3 homoeopathic consultations (and 6 inactive powders) and 3 consultations of psychological counselling (Cognitive therapy and Behavioural therapy). In the Placebo group 13 participants completed the 4 week trial, which included 3 homoeopathic consultations (and 6 inactive powders).

In depth interviews were conducted with each of the participants at each consultation and full physical examination to exclude other disease conditions.

At the beginning of each consultation the participants were required to complete the Hamilton Anxiety Rating Scale (Appendix F), the Beck Anxiety Inventory (Appendix G), and the Patient Perception Questionnaire (Appendix H).

The groups were then compared to each other to determine if any group responded more favourably, thus indicating a more effective corresponding intervention i.e., Simillimum, Psychological Counselling or Placebo in treatment of GAD.

Data was analyzed using SPSS Version 13.1. Quantitative analyses were conducted

using non-parametric methods due to the small sample size. Intra-group comparisons were made using the Wilcoxon Signed rank test. Inter-group comparisons were made using Kruskal Wallis Test.

Results: Intra-group results for the comparison of baseline and final consultation were as follows:

- ✚ Homoeopathic Simillimum as measured by HAM-A ( $p= 0.068$ ) i.e. no significant difference.
- ✚ Psychological Counselling as measured by HAM-A ( $p=0.008$ ) i.e. a significant difference.
- ✚ Placebo as measured by HAM-A ( $p=0.003$ ) i.e. a significant difference.
  
- ✚ Homoeopathic Simillimum as measured by BAI ( $p=0.153$ ) i.e. no significant difference.
- ✚ Psychological Counselling as measured by BAI ( $p=0.005$ ) i.e. a significant difference.
- ✚ Placebo as measured by BAI ( $p=0.002$ ) i.e. a significant difference.
  
- ✚ Homoeopathic Simillimum as measured by PQ1Total ( $p=0.033$ ) i.e. a significant difference.

- ✚ Psychological Counselling as measured by PQ1 Total ( $p=0.008$ ) i.e. a significant difference.
- ✚ Placebo as measured by PQ1 Total ( $p=0.002$ ) i.e. a significant difference.
  
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- ✚ Homoeopathic Simillimum as measured by PQ4 ( $p=0.121$ ) i.e. no significant difference.
- ✚ Psychological Counselling as measured by PQ4 ( $p=0.012$ ) i.e. a significant difference.
- ✚ Placebo as measured by PQ4 ( $p=0.256$ ) i.e. no significant difference.

Inter-group results were analyzed per consultation. None of the results were less than

or equal to ( $p=0.05$ ) therefore, none were significant.

The results of this study lead to the conclusion that homoeopathic simillimum treatment is no more effective than psychological counselling (CT and BT) or placebo in the management of GAD.

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## **List of abbreviations**

<b>GAD:</b>	Generalized Anxiety Disorder
<b>BT:</b>	Behavioral Therapy
<b>CT:</b>	Cognitive Therapy
<b>HAM-A:</b>	Hamilton Anxiety Rating Scale
<b>BAI:</b>	Beck Anxiety Inventory
<b>PPQ:</b>	Patient Perception Questionnaire
<b>PQ1 Total:</b>	Perception Questionnaire total in Question 1
<b>PQ2:</b>	Perception Questionnaire in Question 2
<b>PQ3:</b>	Perception Questionnaire in Question 3
<b>PQ4:</b>	Perception Questionnaire in Question 4

## Definition of Terms

**Aggravation:** An increase in severity of symptoms in response to external events, internal events such as changes in body functioning or to the administration of a medicine or other therapeutic intervention (Swayne, 2000: 5).

**Antidote:** used in homoeopathy to describe the action of one medicine inhibiting or counteracting the effect of another, or of any other substance counteracting the effect of a medicine. The effect of an antidote may be to slow down, arrest or reverse the action which it opposes. Three general types of antidotes to the action of homoeopathic medicines can be distinguished:

1. physical antidotes (e.g. hot or cold application, compresses, massage)
2. chemical antidotes (e.g. coffee, alcohol, camphor) and
3. dynamic antidotes (e.g. homoeopathic medicines chosen according to actual symptoms, also known as homoeodotes (Swayne, 2000: 13).

**Anxiety:** This is an unpleasant emotional state that has less than a clear source. It is often accompanied by physiological and behavioural changes similar to those caused by fear, or a response to stress, such as the break up of an important relationship or exposure to a life threatening disaster (Berkow, 1997: 395).

**Anxiolytic:** A pharmaceutical product which reduces anxiety and exerts a calming effect with little or no effect on motor or mental functions. It is used in acute anxiety

states for sedative and minor tranquilizing capabilities (Swanson and Block, 1997: 276).

**Avogadro's number:** Amedeo Avogadro (1776 -1856) demonstrated that the number of molecules in one mole of any substances is  $6.0255 \times 10^{23}$ . Avogadro's number is of interest to homoeopathy because it specifies the potency at which a remedy no longer contains any of the original material substance

(Swayne, 2000: 22).

**Behaviour therapy:** Behaviour therapy targets the patient's behaviour and emphasizes treatment in the context of family and school instead of focusing on intra-psychic conflict (Allwood and Gagiano, 1997: 256).

**Centesimal Scale "C":** A method of potentising based on the principal that the first potency should contain one hundredth part of the base substance and each succeeding potency should contain one hundredth of the one immediately preceding (Centesimal potencies are denoted by suffixing "C" to the numerals denoting the deconcentration stage of the drug) (Gaier, 1991: 448).

**Cognitive therapy:** This model sees mental disorders as resulting from disorders in people's cognitions and thoughts. The aim of cognitive therapy is to demonstrate to people seeking treatment that their distorted or irrational thoughts are the main contributions to their difficulties. If the faulty modes of thinking can be modified or changed, then disorders can be alleviated (Campbell, 1996: 746).

**Effectiveness:** The extent to which a specific intervention, procedure or regime does what it is intended to do for a specified population, when deployed in the field in routine circumstances (Swayne, 2000: 77).

**Efficacy:** The extent to which a specific intervention, procedure or regime does what it is intended to do for a specified population, when applied in ideal circumstances (Swayne, 2000: 77).

**Generalized Anxiety Disorder:** Generalized Anxiety Disorder (GAD) is defined as excessive and pervasive worry, accompanied by a variety of somatic symptoms that causes significant impairment in social or occupational functioning or marked distress in the patient (DSM IV, 1994: 432).

**Homoeopathy:** The word homoeopathy is derived from the words *homoios* meaning 'similar' and *pathos* meaning 'suffering'. The giving of a similar medicine to treat illness is ancient and predates homoeopathy. It is a science and an art that is based on the realm of modern quantum physics. It is holistic in concept, utilizes dietary changes, vitamin therapy, herbalism and psychotherapy. Nevertheless, its holistic approach does not consist of putting together a vast number of different treatments. Homoeopathy is a system of medicine and an alternative approach to treating illness (Bloch, 2003: 24-25).

**Homoeopathic drug preparation:** The three processes of homoeopathic drug preparation are:

1. Serial dilution;
2. Succussion and;
3. Trituration.

Dilution reduces the toxicity of the original crude drug by serialized deconcentrations.

Serial dilution means that each is prepared from the dilution that immediately came before it. Succussions for soluble drugs, and triturating for insoluble medicines, are the mechanical methods that impart the pharmacological message of the original substance (active principles) to the water molecules of the solvent or diluent respectively (Gaier, 1991: 138).

**Individualization:** To particularize medicine for any one patient (Gaier, 1991: 283).

**Infinitesimal dose:** A dose of medicine whose source material has been diluted beyond Avogadro's number (Swayne, 2000: 112).

**LM Potency:** Potencies based on a dilution factor of 1:50 000, as compared to 1:10 (decimal potency) and 1:100 (centesimal potency) (Swayne, 2000: 127).

**Materia Medica:** This is a systemic documentation of the description of the nature and the therapeutic repertoire of homoeopathic medicines, of the pathology, the symptoms and signs and their modifying factors, and general characteristics of the patient

associated with them, derived from their toxicology, homoeopathic pathogenic trials and clinical experience of their use

(Swayne, 2000: 132-133).

**Miasm:** A miasm is any inherent weakness or tendency to disease. It means a mist, indicating both it's dynamic and it's subtle, and all pervading nature. Miasms work deeply and over long period of time, even over several generations. They work to change us so that we become more susceptible to diseases new and old (Roberts, 1993: 38).

**Pharmacology:** This is the study of drugs - what they are, how they work and what they do. It is the study of the effect of chemical agents on living processes (Laurence and Carpenter, 1994: 166).

**Pharmacopoeia:** A book (especially one officially published) containing lists of drugs with standards of manufacture, purity, assay and directions for use (Laurence and Carpenter, 1994: 166).

**Placebo:** A substance with no active biological properties, knowingly or unknowingly used to exert a beneficial therapeutic effect, or given to satisfy a patient's expectations of treatment. An inactive agent used for comparison with the substance or method to be tested in a controlled trial, and indistinguishable from it (Swayne, 2000: 162).

**Potency:** The power, vitality, strength, or dynamis which a homoeopathic remedy possesses, often represented as a number attached to the remedy name, either immediately before or after. The potency of the remedy comes as a result of the succession step in the remedy preparation process (Yasgur, 1998:193).

**Potentisation:** A multi-step process developed by Hahnemann by which the medicinal power (potency) of a homoeopathic medicine is released or increased, involving serial dilution with succussion, or using trituration or fluxion.

It is characterized by the following features:

1. It is a purely mechanical and mathematico-physical process.
2. The procedure involves neither uncertain, unreliable nor immeasurable factors.
3. The resultant product is stable and can readily be maintained that way.
4. The process is theoretically illimitable, though it becomes laboriously time-consuming in the higher range of potencies (Gaier, 1991: 441).

**Psychometrics:** The branch of psychology dealing with measurable factors. They measure a wide variety of attributes and characteristics (Rust and Susan, 1989: 1-10, 143).

**Quantitative analysis:** The numerical representation and manipulation of observations, for the purpose of describing and explaining the phenomena that those observations reflect (Neuman, 1999: 418).

**Repertory:** A book listing all the symptoms that have been elicited during a proving as well as clinical verifications. It contains the remedies in a graded format as well as references to the authority involved. A repertory is essential for detailed prescribing (Bloch, 2003: 30).

**Simillimum:** The unique remedy that corresponds exactly to the presenting symptomatology of the patient. There can only be one simillimum for each dis-ease. Homoeopathic medicine is based on the empirical principle that substances capable of causing disorder, symptomatic, functional or pathological, physical or psychological, in healthy objects can be used as medicines to remedy similar patterns of disorder experienced by people (animals) when they are ill. This is the defining principle of homoeopathy (Hubbard, 1990: 3).

**Susceptibility:** Capacity, proneness or disposition to be affected (Gaier, 1991: 536).

**Suppression:** Suppression is the deliberate attempt to remove symptoms regardless of their true inner cause or the greater needs of the person as a whole. The Peripheral Disturbance is removed but the Central Disturbance which is causing it is untouched. If the causal factor remains, it will produce symptoms again, either the same symptoms or, if the treatment has been detrimental, even worse (inner) symptoms and a new more harmful local disease picture results (Roberts, 1993: 38).

**The Model of Layers:** As mankind becomes afflicted by more and more morbidic influence, these tend to build layers of disease susceptibility. Miasms build one upon another representing a deepening of ill health. The vital force now seeks more complex means to defend against the complexities of our present condition of ill health (Roberts, 1993: 74).

**Treatment:** Any deliberately applied intervention for diagnostic, therapeutic or prognostic purposes in patient care, in a clinical study or as an intervention on a healthy subject in a pharmacological investigation. It's a procedure used in care of a patient (Mosby, 2002: 1744).

**Trituration:** One of the processes of homoeopathic drug preparation. It is the act of prolonged grinding with a pestle in a mortar (or a similar mechanical procedure) to reduce a homoeopathic drug to a fine powder while amalgamating it thoroughly with saccharum lactis (sugar of milk) by rubbing the two together under the pestle in the mortar (Gaier, 1991: 559).

# CHAPTER ONE

## Introduction

Generalized Anxiety Disorder (GAD), is defined in the *Diagnostic and Statistical Manual of Mental Disorders (DSM-IV)* as excessive and pervasive worry, accompanied by a variety of somatic symptoms, that causes significant impairment in social or occupational functioning or marked distress in the patient (Kaplan and Sadock, 1996: 214).

In a current report a survey found that anxiety disorders represents the largest mental health problem in the general population, with an incidence of anxiety disorders being 12, 6 % of the general population or greater. Consequently it may be assumed that millions of South Africans experience an anxiety disorder. This disorder is unlikely to remit without treatment. Symptoms may begin early or late in life, but findings suggest that they usually persist after onset. Given the chronicity of the disorder, development of new, more effective treatment is crucial (Kimberly, 2003).

According to Kessler and Wittchen (2002:6), GAD is more commonly found among women than men and among people of various disadvantaged social statuses (e.g. low income and education, racial or ethnic minorities) compared with their more socially advantaged counterparts with the highest current prevalence of GAD found among people in the middle years of life.

Despite the prevalence of GAD, little is known of its natural course, as Keller (2002: 11)

states that the duration of illness exceeds that required for its diagnosis (presence of symptoms for at least 6 months), and at present GAD is poorly recognized and is consequently often under treated.

Patients with GAD are more likely to present in a primary health care setting than to a psychiatrist. They are likely to complain of somatic symptoms, and may be referred for unnecessary medical investigations. Patients with GAD may present co-morbid mood, anxiety, or substance-use disorders. Untreated, GAD is a chronic condition. The course is likely to depend on co-morbid disorders. Negative life events are likely to exacerbate symptoms. Treatment may significantly benefit patients (Robertson, Allwood and Gagiano, 2001: 148).

Barlow and Durand (1995: 164) state that many primary care physicians treat Generalized Anxiety Disorder exclusively by prescribing anti-anxiety medication. However, these drugs are not without risks. They cause impairment of cognitive functioning such as reaction time and many individuals experience rebound anxiety if they abruptly stop taking the medications (Barlow and Durand 1995: 164).

## **1.1 Problem Statement**

📁 The aim of this double-blind placebo-controlled study was to evaluate the relative efficacy of homoeopathic simillimum treatment as compared to psychological counselling (Cognitive Therapy and Behavioural Therapy) in the management of Generalized Anxiety Disorder, by means of the Hamilton Anxiety Rating Scale (Appendix F), the Beck Anxiety Inventory (Appendix G) and the Patient Perception Questionnaire (Appendix H).

## **1.2 Objectives of the study**

### **1.2.1 The first objective**

The first objective was to determine the effectiveness of homoeopathic simillimum treatment, psychological counselling (Cognitive Therapy and Behavioural Therapy) and placebo in the management of GAD signs and symptoms in terms of the Hamilton Anxiety Rating Scale (refer Appendix F).

### **1.2.2 The second objective**

The second objective was to determine the effectiveness of homoeopathic simillimum treatment, psychological counselling (Cognitive Therapy and Behavioural Therapy) and placebo in the management of GAD signs and symptoms in terms of the Beck Anxiety Rating Scale (refer Appendix G).

### **1.2.3 The third objective**

The third objective was to determine the effectiveness homoeopathic simillimum treatment, psychological counselling (Cognitive Therapy and Behavioural Therapy) and placebo in the management of GAD signs and symptoms in terms of the Patient Perception Questionnaire (refer Appendix H).

### **1.2.4. The fourth objective**

The fourth objective was to compare the effectiveness of the three groups (Simillimum group, Psychological Counselling group and Placebo group) with each other with regard to the three measurement tools.

## **1.3 Statement of hypotheses**

### **1.3.1 The first hypothesis**

It was hypothesized that Homoeopathic simillimum would have no beneficial effect in the management of GAD signs and symptoms in terms of the Hamilton Anxiety Rating Scale (refer Appendix F), the Beck Anxiety Inventory (refer Appendix G) and the Patient Perception Questionnaire (refer Appendix H).

### **1.3.2 The second hypothesis**

It was hypothesized that Psychological counselling would have no beneficial effect in the management of GAD signs and symptoms in terms of the Hamilton Anxiety Rating Scale (refer Appendix F), the Beck Anxiety Inventory (refer Appendix G) and the Patient Perception Questionnaire (refer Appendix H).

### **1.3.3 The third hypothesis**

It was hypothesized that Placebo would have no beneficial effect in the management of GAD signs and symptoms in terms of the Hamilton Anxiety Rating Scale (refer Appendix F), the Beck Anxiety Inventory (refer Appendix G) and the Patient Perception Questionnaire (refer Appendix H).

### **1.3.4 The fourth hypothesis**

It was hypothesized that there would be no difference in effect between the three groups in the management of GAD.

## CHAPTER TWO

### Review of the related literature

#### **2.1 Definition**

Generalized Anxiety Disorder (GAD), is defined in the *Diagnostic and Statistical Manual of Mental Disorders (DSM-IV)* as excessive and pervasive worry, accompanied by a variety of somatic symptoms, that causes significant impairment in social or occupational functioning or marked distress in the patient (Kaplan and Sadock, 1996: 214).

According to Kessler and Wittchen, (2002: 6), GAD is more commonly found among women than men and among people of various disadvantaged social statuses (e.g. low income and education, racial-ethnic minorities) compared with their more socially advantaged counterparts, with the highest current prevalence of GAD found among people in middle years of life.

Despite the prevalence of GAD, little is known of its natural course, but Keller (2002:11) states that although retrospective analyses suggest that the duration of illness exceeds that required for its diagnosis (presence of symptoms for at least 6 months) the data obtained from cross-sectional, retrospective, or epidemiologic analyses or randomized clinical studies may be subject to limitations.

At present, GAD is poorly recognized and is consequently often under-treated. In the recent years, there has been an increasing trend toward the use of antidepressants.

Although generalized anxiety disorder (GAD) is a common disorder associated with significant levels of morbidity, little is known of its long-term course and outcomes.

During the first 5 years, GAD follows a chronic course with low rates of remission and moderate rates of relapse/recurrence following remission. However GAD is currently under-recognized and under-treated, but according to Keller (2002: 11) it is hoped that this will change with the ever-increasing awareness of anxiety disorders.

## **2.2 Theories of Anxiety**

### **2.2.1 Conditioning Theory**

Mowrer's two-stage theory for the acquisition and maintenance of fear and anxiety and avoidance behaviour has greatly influenced thinking about anxiety. According to the two-stage theory, a neutral event comes to trigger anxiety if it has been experienced along with an event that itself causes anxiety. Once fear of a previous neutral stimulation is acquired in this way, methods of escape or avoidance are attempted and successful methods are learned and maintained. This learning to escape and avoid is the second stage of the hypothesized two-stage process: instrumental or operational conditioning (Friedman, 1998:130).

### **2.2.2 Cognitive Theory**

This theory postulates that what people think influences how they feel. Beck and his colleagues have hypothesized that unrealistic expectations and attitudes, represented as cognitive “Schemas”, predispose a person to emotional distress (Friedman, 1998:130-131).

### **2.2.3 Biological Theory**

This emphasizes the role of the nervous system in anxiety. Selye introduced the concept of a General Adaptation Syndrome (GAS), which describes physical reactions to stressors. Accordingly, there are three phases in the reaction to stress.

First phase - alarm reaction.

Second phase - resistance.

Third phase - exhaustion.

Other researchers have emphasized the importance of interpretation of events in the environment (Carson, Butcher and Mineka, 1996:176-181).

### **2.2.4 Genetic and Evolutionary Theory**

Anxiety is believed to have survival value because it prepares the organism to avoid harm. Chronic anxiety can involve hyper-vigilance and exaggerated perception of the number and severity of dangerous environmental stimuli (Friedman, 1998:130-131). Anxiety is especially prevalent in relatives of anxious individuals. Genetic and family studies have found some support for this notion. Various genetic studies point out to a

component of heritability for anxiety (Friedman, 1998:130-131).

## **2.3 Aetiology**

As with many mental disorders, the cause of GAD is not known. As currently defined, GAD probably affects a heterogeneous group of patients. Perhaps because a certain degree of anxiety is normal and adaptive, differentiating normal anxiety from pathological anxiety and differentiating biological causative factors from psychological factors are difficult. Biological and psychological factors probably work together (Kaplan and Sadock, 1996:214).

It is said that a number of events can cause GAD, although it is believed that some people are genetically predisposed to developing it. An important twin study has strengthened this suggestion. It was found that the risk of GAD was somewhat greater in monozygotic (identical) female twins than in dizygotic female twins when one twin already had GAD (Barlow and Durand, 1995: 162).

According to Andreason, Black and Donald (1995: 303-306), other causes can include childhood psychological traumas, moving, changing jobs, divorce, or the death of a loved one.

Beck suggests that GAD may result from a series of precipitating psychological factors:

1. Increased demands upon the individual, who perceives a threat to important values, and depletion in coping resources leading to greater expectations, increased responsibilities and an overall increase in energy output.
2. Increased threat to life, or to one's domestic situation, can contribute to the development of GAD.
3. Stressful events which undermine the individual's confidence, for instance failing exams, rejection by one's partner, or a relatively minor car accident (Powell and Enright, 1990: 29).

## **2.4 Epidemiology**

Generalized Anxiety Disorder is a common condition. Reasonable estimates for the one-year prevalence of generalized anxiety range from 3 to 8 percent. GAD is probably the disorder most often found with a coexisting mental disorder, usually another anxiety disorder or a mood disorder. The ratio of women to men is about 2 to 1, but the ratio of women to men who are receiving inpatient treatment for the disorder is about 1 to 1. The age of onset is difficult to specify, since most patients with the disorder report that they have been anxious for as long as they can remember (Kaplan and Sadock, 1996:214).

Patients usually come to a clinician's attention in their 20's, although the first contact with a clinician can occur at virtually any age.

Only a third of patients who have GAD seek psychiatric treatment. Many patients go to general practitioners, internists, cardiologists, pulmonary specialists, or gastroenterologists, seeking treatment for the somatic component of the disorder (Kaplan and Sadock, 1996:214).

Anxiety in its various forms is very prevalent in the elderly. Himelfarb and Murrell (1984:159-167), in a study of the prevalence and correlation of anxiety symptoms in older adults, found that 17% of elderly men and 21,5% of elderly women surveyed in a community sample were found to have sufficiently severe anxiety symptoms to warrant treatment.

The elderly may be particularly susceptible to developing anxiety as failing health or other life situations begin to strip them of whatever remaining control they have over events in their lives (Barlow and Durand, 1995: 162).

## **2.5 Pathophysiology of anxiety**

Borkovec and other researchers (1993, 611-619) noticed that, although the peripheral autonomic arousal of individuals with GAD is restricted, the evidence showed marked increases in EEG beta activity, reflecting intense cognitive processing in the frontal

lobes of their brains.

This finding suggests that people with GAD are engaging in intense thought processes or worry. In this way they seek to avoid negative affect associated with their threat.

Although they may avoid much of the unpleasantness and pain associated with the negative affect and imagery, they are never able to work through the problems that they face and arrive at solutions. Therefore they become chronic worriers with accompanying autonomic inflexibility and quite severe muscle tension (Kendall and Hanmen 1998: 40-48, 165-166).

## **2.6 Signs and symptoms**

According to Oltomanns and Emery (1995: 206-207), the primary symptoms of Generalized Anxiety Disorder are:

- Anxiety: anxiety is excessive and interferes with other aspects of the patient's life.
- Motor tension: it is most commonly manifested as shakiness, restlessness, and headaches.
- Autonomic hyperactivity: this is commonly manifested by shortness of breath, excessive sweating, palpitations, and various gastrointestinal symptoms.
- Cognitive vigilance: this is evidenced by the patient's irritability and the ease with which the patient is startled.

## **2.7 Diagnosis**

The essential feature of generalized anxiety disorder is excessive worry and anxiety that has been present for at least 6 months, about many events or activities. This anxiety is out of proportion to the likelihood of the feared event and is difficult to control. It causes distress or impairs the persons functioning (DSM-IV, 1994: 433).

Although GAD is a subjective experience of apprehension, anxiety, and tension, this condition is often associated with behavioural and physiological indices such as motor tremor, rapid eye-blinks, urinary frequency, loss of appetite, concentration difficulties, restlessness, and other symptoms of increased activity of the sympathetic nervous system. Muscular aches and pains, fatigue, stomach cramps, indigestion, lack of concentration, impatience and irritability are typical spin-offs arising out of feelings of anxiety and dread (Franks, 1996: 31). These indices are vital clues in making a diagnosis of GAD.

According to the DSM-IV (300.02) the diagnostic criteria for Generalized Anxiety Disorder are:

- A. Excessive anxiety and worry (apprehensive expectation), occurring more days than not for at least 6 months about a number of events or activities (such as work or social performance).
- B. The person finds it difficult to control the worry.

- C. The anxiety and worry are associated with three (or more) of the following six symptoms (with at least some symptoms present for more days than not in the past 6 months).
1. restlessness or feeling keyed up or on edge,
  2. being easily fatigued,
  3. difficulty concentration or mind going blank,
  4. irritability,
  5. muscle tension,
  6. sleep disturbance (difficulty falling or staying asleep, or restless unsatisfying sleep).
- D. The focus of the anxiety and worry is not confined to features of an AXIS I disorder, e.g. the anxiety or worry is not about having a panic attack (as in Panic Disorder), being embarrassed in public (as in Social Phobia), being contaminated (as in Obsessive Compulsive Disorder), being away from home or close relatives (as in Separation Anxiety Disorder), gaining weight (as in Anorexia Nervosa), having multiple physical complaints (as in Somatisation Disorder), or having serious illness (as in Hypochondriasis), and the anxiety and worry do not occur exclusively during Post-traumatic Stress Disorder.
- E. The anxiety, worry or physical symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.
- F. The disturbance is not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition (e.g., hyperthyroidism) and does not occur exclusively during a Mood Disorder, a psychotic Disorder, or a Pervasive Developmental Disorder.

The person finds it difficult to keep worrisome thoughts from interfering with attention to tasks at hand and has difficulty stopping the worry. Adults with generalized anxiety disorder often worry about everyday, routine life circumstances, whereas children tend to worry excessively about their competence or the quality of their performance (DSM IV, 1994:433).

## **2.8 Differential diagnosis**

The differential diagnosis of GAD includes all the medical disorders that may cause anxiety, such as hyperthyroidism, caffeinism and cardiac arrhythmias. It is necessary to rule out the presence of co-morbid psychiatric, medical disorders, mood disorders such as depression and dysthymia, and other anxiety disorders. In addition, attention should be paid to the possibility of co-morbid somatization disorder or substance abuse, dependence, or withdrawal. In particular, excessive alcohol and caffeine use may contribute to chronic anxiety symptoms and should be excluded (Stein, Seedat, Niehaus, Pienaar and Emsley: 2000: 109).

The co-morbid disorders are:

- Anxiety disorder due to a general medical condition
- A Substance-Induced anxiety disorder
- Panic Disorder
- Social Phobia

- Obsessive-Compulsive Disorder
- Anorexia Nervosa
- Hypochondriasis
- Somatization Disorder
- Separation Anxiety Disorder
- Post-traumatic Stress Disorder
- Adjustment Disorder

(DSM-IV, 1994:434-435).

## **2.9 Assessment Methods**

### **2.9.1 Measurements**

According to Friedman (1998: 132), the methods of assessing anxiety include interviews, questionnaires, physiological monitoring and observations of behaviour.

These can be used to assess the full range of anxiety, from mild to intense. The primary technique used to assess pathological anxiety is the clinical interview addressing criterion symptoms as specified in DSM-IV.

However, individuals are often inconsistent in their observations of themselves; the usefulness of their reports depends heavily on their limited powers of self-observation.

Therefore, scales and questionnaires have been developed to measure anxiety (Friedman, 1998:133). Mental measurement is used to gain understanding of an

individual so as to be able to predict behaviour and provide a basis for future action.

Psychometrics are tools which assist in the diagnosis of a range of abnormal conditions (Edenborough, 1994, 1999: 1-8).

In this study the following tools were used: the Hamilton Anxiety Rating Scale (Appendix F), the Beck Anxiety Inventory (Appendix G), and the Patient Perception Questionnaire (Appendix H).

### **2.9.2 Hamilton Anxiety Rating Scale (HAM-A)**

This is the standard method of assessing the effectiveness of drug treatments in psychiatric indications, particularly anxiety and depression. The scale is internationally recognized by drug regulatory bodies. It is a rating scale that is developed to quantify the severity of anxiety symptomatology and is often used in psychotropic drug evaluation. It consists of 14 items, each defined by a series of symptoms. Each item is rated on a 5-point scale, ranging from 0 (not present/ absent) to 4 (incapacitating) (Hamilton, 1959).

### **2.9.3 Beck Anxiety Inventory (BAI)**

This scale was developed to address the need for an instrument that would reliably discriminate anxiety from depression while displaying convergent validity. It is also useful in differentiating between behavioural, emotional, and physiological symptoms in

individuals with anxiety and depression. It quickly assesses the severity of patient anxiety. The scale has obtained high international consistency and item total correlations. It is more reliable compared to existing self-report measures, which have not yet been shown to differentiate anxiety from depression adequately.

This scale consists of 21 items, each describing a common symptom of anxiety. The respondent is asked to rate how much he/she has been bothered by each symptom over the past week on a 4-point scale ranging from 0 (not at all) to 3 (severely). It is recommended for use in assessing anxiety in clinical and research settings (Beck, Epstein, Brown and Steer, 1987: 1).

#### **2.9.4 Patient Perception Questionnaire**

Due to the descriptive nature of GAD, subjective outcome measures also have value. It is known that the emotions of anxiety cannot be only objectively measured. Anxiety can also be estimated by an anxiety perception questionnaire, which estimates the client's current severity of GAD. Such a questionnaire also measures the extent to which GAD affects daily functioning and noticeability to others (Bonne, Shemer, Goral, Katz and Shalev, 2003: 282-7).

The anxiety perception questionnaire used in this study is called the Patient Perception Questionnaire (Appendix H), and is adapted from Morin (1993: 199).

## **2.10 Treatment**

## **2.10.1 Pharmaceutical treatment**

Many primary care physicians treat GAD exclusively by prescribing anti-anxiety medication. However, these drugs are not without risks. They cause impairment of cognitive functioning such as reaction time. Many individuals experience rebound anxiety if they abruptly stop taking the medications. At the present time most clinical investigators think these drugs may have some beneficial effects in reducing anxiety over short term (4 to 8 weeks), compared to placebo, but not over the long term (Gorman, 2002: 17).

### **2.10.1.1 Anxiolytics**

Anti-anxiety agents (also known as anxiolytics or minor tranquilizers) include the following classes: benzodiazepine, carbamate, azaspirodecanedione, and barbiturate.

#### **2.10.1.1.1 Benzodiazepines**

Benzodiazepines became widely available in the 1960's. They all have anxiolytic, hypnotic, anticonvulsant, and muscle relaxant properties, which are mediated by potentiating the effect of gamma-aminobutyric acid.

Benzodiazepines are anxiolytic in patients with GAD and have a rapid onset of action.

However, their efficacy in long-term treatment may not be as robust as previously assumed. For example, Gorman (2002: 18) found that of patients responding to treatment, nearly two thirds will remit and a number of studies have indicated that, despite early improvement in anxiety symptoms, the effects of benzodiazepines are not significantly different from placebo after 4 to 6 weeks of treatment. Moreover, their benefit extends primarily to relief of somatic symptoms, rather than the psychological symptoms that include worry, a key feature of GAD (Gorman, 2002: 18).

Adverse events while on this drug include:

- impairment of cognitive and motor functioning,
- impairment of driving performance,
- increased number of falls resulting in hip fractures in the elderly.

(Barlow and Durand, 1995: 164.)

There is also a concern that this class of drugs may lead to dependence, resulting in withdrawal symptoms, sedation, difficulty concentrating and other bothersome side effects (Pande, Crockatt, Feltner, Janney, Smith, Weisler, Londborg, Bielski, Zimbroff, Davidson and Liu-Dumaw, 2002: 533). According to Stevens and Rodin (2001: 35-37), the benzodiazepines may produce functional changes in the central nervous system that make it difficult for patients to withdraw from these drugs

Binding of GABA to the receptor on the cell membrane triggers an opening of a chloride conductance. The influx of chloride ions causes a small hyper polarization that removes the post-synaptic potential away from its firing threshold and thus inhibits the formation

of action potential.

The benzodiazepines bind to specific, high affinity sites on the cell membrane, which are separate from but adjacent to the receptor for GABA.

The benzodiazepine receptors are found only in the central nervous system (CNS), and their location parallels that of GABA neurons.

Benzodiazepines and GABA mutually increase the affinity of their binding sites without actually changing the total number of sites (Mycek, Harvey and Champe, 2000: 89-92).

#### **2.10.1.1.2 Carbamate**

These drugs include meprobamate, ethinamate, and carisoprodol, which have been used in the past as anxiolytics. They have more potential for abuse and are more likely to induce dependence than the benzodiazepines. Carbamate therapy is indicated only when use of benzodiazepine is not possible (Fadem, 1994: 23).

#### **2.10.1.1.3 Buspirone**

Buspirone, an azaspirodecanedione, is unrelated to the benzodiazepines. It is unique among anxiolytics in that it is non-sedating and is not associated with dependence, abuse, or withdrawal problems (Fadem, 1994: 23).

#### **2.10.1.1.4 Barbiturates**

These drugs have a lower therapeutic index (the ratio of minimum toxic dose to maximum effective dose) than the benzodiazepines, and have a greater potential for abuse. Therefore, they are less frequently used as anti-anxiety drugs. Adverse effects include sedation and respiratory depression. Overdose of barbiturates may be lethal. Tolerance and dependence develop with chronic use (Fadem, 1994: 23).

#### **2.10.1.2 Antidepressants and other drugs**

Recently, management of GAD has shifted from benzodiazepines toward antidepressants such as venlafaxine, driven by the recognition that:

- the antidepressants have anti-anxiety effects,
- depressive symptoms that sometimes accompany GAD may not respond well to benzodiazepines, and
- Benzodiazepines, despite their long record of safety, do carry some risk of abuse, dependence, and associated problems such as withdrawal effects.

However, the delayed onset of clinical effect seen with antidepressant drugs and buspirone is a limitation and disadvantage compared with benzodiazepines, which are rapidly effective in many GAD patients.

Pregabalin claims to be effective, rapidly acting, and safe treatment for GAD. In short-term treatment, pregabalin does not appear to have the withdrawal symptoms associated with the benzodiazepines (Pande et al., 2002: 533).

Selective Serotonin Re-uptake Inhibitors type of drugs are not considered as frontline drugs for treating anxiety, because of their side effects which include nausea, headaches, and sexual side effects (Pande et al., 2002: 533).

## **2.10.2 Psychological counselling**

Kaplan and Sadock (1996: 216), state that the major psychotherapeutic approaches to GAD are cognitive-behavioural, supportive, and insight oriented. Data is still limited on the relative merits of those approaches, although the most sophisticated studies have been with cognitive-behavioural techniques, which seem to have both short-term and long-term efficacy.

### **2.10.2.1 Behavioural therapy (BT)**

Behaviour therapy emerged in the late 1950s as an explicitly formulated, systematized body of knowledge. It was not until the 1960s that behaviour therapy was widely recognized as an alternative model of aetiology and therapy to the prevailing psychodynamic approach. As a scientific approach to human problems, behaviour therapy is characterized by an emphasis on rigorous measurement and carefully controlled experiments both in the laboratory and in the natural environment. An attempt is made to objectively evaluate the results of therapeutic interventions rather than to rely primarily on the therapist's clinical or subjective impression of progress. The focus is on

observable and hence directly measurable behaviour (O'Leary and Wilson, 1975: 12).

One of the unique contributions of behaviour therapy is that it provides the therapist with well-defined system of procedures to employ within the context of a well-defined role. It also provides the client with a clear role, and it stresses the importance of client awareness and participation in the therapeutic process. Clients must be willing to cooperate in carrying out therapeutic activities, both during therapy sessions and in their life. If they are not involved in this way, the chances are slim that therapy will be successful (Corey, 1996: 289).

Behaviour therapy targets the patient's behaviour and emphasizes treatment in the context of family and school instead of focusing on intra-psychic conflict, and is combined with cognitive-behaviour therapy which combines a behavioural approach with changing the cognitions associated with the patient's anxiety. The combination of these therapies has shown positive results without the drawbacks of medication (Stevens and Rodin, 2001: 35-37).

Limitations and criticisms of behaviour therapy: behaviour therapists need to listen very carefully to their clients and to allow them to express and explore their feelings before implementing a treatment plan. The basic therapeutic conditions that are stressed by the person-centred therapists such as active listening, accurate empathy, positive regard, genuineness, respect, and immediacy can be integrated into a behavioural framework. However, too often counsellors are so anxious to work toward resolving problems that they are not fully present with their clients. A mistake that some

counsellors make is focusing on the presenting issue instead of listening to the client's deeper message (Corey, 1996: 308).

### **2.10.2.2 Cognitive therapy (CT)**

According to Corey (1996, 318-359), the cognitive force in psychotherapy has been an increasingly important one over the decades. The number of variations on this basic meta-cognitive approach (thinking more about one's thinking) attests to the vitality of the cognitive model.

Cognitive therapy strives to uncover and examine cognitions associated with psychological dysfunction. Its aim is to foster more adaptive, accurate thinking by modifying dysfunctional cognitive structures and processes. The roots of cognitive therapy are in cognitive psychology, structural theory and depth psychology, and the phenomenological approach to psychology (Corey, 1996: 318-359).

Cognitive therapy is very collaborative and empirically focused. Collaboration is seen in four aspects of cognitive therapy: the therapist and client setting an agenda for each session, the therapist providing a rationale for intervention, the therapist eliciting feedback in each session, and the therapist and client as a team investigating the client's cognitions to test their accuracy and adaptiveness (Kuehlwein and Rosen, 1993: 9).

Cognitive therapy places major emphasis on behavioural experiments i.e., testing one's ideas by the scientific method. In these experiments the client specifies clearly the belief to be tested, determines the grounds for acceptance and rejection of the theory, performs the action, and compares the data with those the client expected (Peterson, 1996:210).

Cognitive therapy seeks to:

1. Identify cognitions relevant to the presenting problem.
2. Recognize connections among cognitions, affects, and behaviours.
3. Examine the evidence for and against key beliefs.
4. Encourage the patient to try out alternative conceptualizations.
5. Teach the patient to carry out the cognitive process independently

(Schuyler, 1991: 29).

The cognitive model's view of abnormality sees mental disorders as resulting from disorders in people's cognitions and thoughts. The aim of cognitive therapy is to demonstrate to people seeking treatment that their distorted or irrational thoughts are the main contributors to their difficulties. If the faulty modes of thinking can be modified or changed, then disorders can be alleviated (Gross and Mcilveen, 1996: 118).

### **2.10.3 Homoeopathy**

Homoeopathy is a therapeutic medical system that originated in the fourth century BC

when Hippocrates (460-350 B.C.) stated that one could cure contraries or by similars. Samuel Hahnemann (1755-1843) created a system that made use of therapeutic principle of similars (Eizayaga, 1991: 11-12) and introduced the method of potentisation, namely, making medicinal preparations by alternating dilution and succession.

Orthodox medicine is concerned with administering medicines/ therapeutic substances in material doses. Homoeopathy involves the stimulation of the patient with an infinitesimal dose of the medicine.

The Arndt-Schultz law states that large doses of poisonous substance may be lethal, a smaller dose of the same substance inhibits and minimal doses can stimulate cellular activity (Swayne, 2000: 16).

In the preparation of homoeopathic remedies the original pharmacological molecules are diluted many times by a factor of 10 (decimal potency) or 100 (centesimal potency) at each dilution step. After each dilution the solution is succussed (shaken vigorously). This step-wise process is known as potentisation (Gaier, 1991: 441).

The physiological activity of potentised preparation lies in the crystalline structure of this water molecule and their ability to absorb and emit radiance at specific frequencies. Dilution progressively removes crystals containing the solute molecule and supplies a fresh source of unstructured water. Succussion causes new water crystals which do not contain a solute molecule to grow in the same pattern as those containing solute

molecules (Towsey and Hasan, 1995).

Maultsby (1998) states that drugs alone cannot be the complete and final answer to good mental health.

According to Hahnemann, "...without the most minute individualization, homoeopathy is not conceivable." (Hahnemann, 1995:34). Homoeopathy aims to quickly restore the diseased patient back to his or her former healthy state, using the least amount of remedies in the smallest dose possible.

It de-emphasizes diagnostic labelling, not because homoeopathic physicians are incapable of speaking the medical jargon, but rather because it is concerned with establishing a cure rather than endless speculating as to the correct medical label for the condition. As homoeopaths use the totality of the patient's symptoms as guide to the remedy prescription, a medical diagnosis of that particular group of symptoms is not a pre-requisite for treatment (Hahnemann, 1995:34).

The homoeopathic method involves an exceptionally complete and detailed description of the patient, the illness and its evolution. It also involves a similarly detailed appraisal of the changes that follow the intervention. Thus it provides an unusually full account of the phenomenon of illness and the healing process (Swayne, 1998: 1-2).

Homoeopathic medicines are versatile; a single medicine is useful in a number of body

systems and a variety of morbidities. Homoeopathic medicines are specific to the precise form in which any type of morbidity is experienced by the patient (Dannheisser and Edwards, 1998: 8-11).

Homoeopathic remedies are tailored not only to the patients' symptoms but also to their personality types and to the reason they became ill. It involves delving into the depths of human nature, and the mental/emotional makeup of the patient. Homoeopathy improves the patient's life on all levels. This is because homoeopathy goes directly to the core of the person, to the body's own natural healing energy (The Vital Force) strengthening it and balancing it, so that not only do the specific disease symptoms disappear, but, ideally, the entire spiritual-mental emotional-physical being is restored (de Schepper, 2001:3-11).

The homoeopathic simillimum is that remedy which most closely corresponds to the totality of symptoms. It is the most similar remedy corresponding to the person, the one best covering the true totality of symptoms. Simillimum treatment is based on a full evaluation of the patient's physical, emotional and mental characteristics. This is especially effective when the disease is chronic (Lockie and Geddes, 1995:14).

The choice of the homoeopathic simillimum (particularly for chronic conditions) rests predominantly upon the mental state or personality subtype of the patient. Anatomical, physiological and biochemical evidence reveals that the body's autonomic, endocrine and immune systems are not autonomous, but engage in an interactive dialogue with

each other and with higher perceptual and emotional centres to maintain health and to combat disease. Hence, it is recognized that psychological factors, such as emotions, stress, distress, play a role in modulating immunity and/or disease process (Pitts and Phillips, 1998: 61-65).

The concept of treating the whole person is an essential element of homoeopathy. The basis of this belief is that symptoms, diseases or pains do not exist in isolation, but are a reflection of how the person as a whole is coping with stress. The homoeopath looks beyond the presenting complaint and the label of the disease to the totality of symptoms the person experiences. Healing from deep trauma comes from facing it openly and retelling the event repeatedly, allowing natural healing mechanisms to operate that are capable of dealing with emotional damage caused by trauma. Such healing mechanisms include crying, laughing and angry raging (Bogorad, 2003)

The correct homoeopathic medicine must accurately reflect the experience of the illness in the individual patient and the individual characteristics of the patient him or herself (Swayne, 1998: 22) (See Figure 2.1).

Human nature is one that seeks pleasure and gratification, so the discomfort and the pain involved in solving problems is avoided as far as possible. Often a person will go to great lengths to avoid such pain, even as far as constructing fantasies in which to live, sometimes to the total exclusion of reality (Peck, 1978).

**SIMILARITY**

**PATHOGENESIS**

**TREATMENT**

**AGENT**

**MEDICINE**

Acts upon: ↓

↑ Identifies:

**SUBJECT**

**PATIENT**

Causing: ↓

↑ Experienced by:

**PATTERN OF DISORDER**

**ILLNESS**

Which comprises: ↓

↑ Which describes:

**DRUG 'PICTURE'**

**CLINICAL 'PICTURE'**

And establishes:

Whose similarity to:

↓

↑

↓ →

→ ↑

**THE MATERIA MEDICA**

## Its therapeutic potential

Figure 2.1 similarities between pathogenesis and treatment (Swayne, 1998: 19)

### **2.10.3.1 The efficacy of homoeopathic treatment of GAD**

According to Sankaran (1994:11-15) a homoeopathic prescription is designed to correct the psychoneuro-endocrine-immunological (P.N.E.I.) or psychogenic disturbance, facilitating improvement of the patient's condition. These four systems are intricately connected to each other, so that specific changes in the psyche can be associated with specific symptoms in the N.E.I. systems, and these systems form together one axis, namely the P.N.E.I. axis (Sankaran,1991: 37).

From the above, one can understand homoeopathy's possible affinity for treating GAD.

A randomized, double blind, placebo-controlled study of Classical homoeopathy in GAD done in Israel in 2003 had positive results in managing GAD, where forty four patients participated in a 10 week trial of individually tailored homoeopathic remedies. Thirty-nine patients completed the study (20 in the active treatment group and 19 in the placebo group). Subject's symptoms were rated before treatment and after 5 and 10 weeks of treatment, with the Hamilton Rating Scale for Anxiety (HAM-A) as the main outcome measure.

Additional measures of outcome included the Brief Symptom Inventory, the Psychological General Well-Being Index, and the Hamilton Rating Scale for Depression,

the Beck Depression Inventory, Spielberger's State-Trait Anxiety Inventory, and a Visual Analogue Scale of subjective distress (Bonne et al., 2003: 282-7).

Positive results were observed for both groups. The conclusion was that the effect of homoeopathic treatment on mental symptoms of patients with GAD did not differ from that of placebo. The improvement in both groups however, was substantial (Bonne et al., 2003: 282-7).

A clinical trial to establish the effectiveness of homoeopathic treatment in conjunction with Rational Behaviour Therapy in the treatment of dysthymic and adjustment disorder was conducted by Louw (2003). This was a double blind clinical trial, which included both quantitative and qualitative methods of analysis. A placebo group was compared with a treatment group, in order to establish whether or not homoeopathic treatment of dysthymic and adjustment disorder, in conjunction with rational behaviour therapy, altered patient score ratings in terms of scales. A total of 18 participants entered the study. The participants were divided into two groups i.e. treatment group (homoeopathic consultations, homoeopathic simillimum powders and rational behaviour group therapy) and placebo group (homoeopathic consultations, placebo powders and rational behaviour group therapy).

Sixteen participants completed the 9-week trial, which included 16 hours of rational behaviour group therapy and a varying number of homoeopathic consultations. Evaluation was by means of the Beck Depression Inventory and the YUPI Scale.

The results according to the Wilcoxon Signed Rank Test (Intra-group analysis) in the Simillimum group for the comparison of the pre and post treatment using the Beck Depression Inventory showed a test score of 0,010 that indicated a statistically significant difference in severity of depression between the first and final treatments. The Placebo group results according to the Wilcoxon Signed Rank Test (Intra-group analysis) for the comparison of the pre and post treatment using the Beck Depression Inventory showed a test score of 0,014 that indicated a statistically significant difference in severity of depression between the first and final treatments.

Whereas the results according to the Wilcoxon Signed Rank Test (Intra-group analysis) for the comparison of the pre and post treatment using the YUPI Inventory – Part A, in the Simillimum group showed a test score of 0,017 that indicated a statistically significant difference in common sense perceptual level between the first and final treatments. However, there was no statistically significant difference in the placebo group as the results showed a test score of 0,050. YUPI Inventory – Part B, in the Simillimum group showed a test score of 0,012 that indicated a statistically significant difference in patient beliefs between the first and final treatments. However, there was no statistically significant difference in the placebo group as the results showed a test score of 0,123.

Homoeopathic simillimum in conjunction with rational behaviour therapy proved statistically superior to placebo in conjunction with rational behaviour therapy in patients with dysthymic and adjustment disorder regarding patients' ability to deal with cognitive

distortions during therapy.

Power, Simpson, Swanson and Wallace (1990: 267-292) conducted a study comparing cognitive-behavioural therapy, diazepam and placebo, alone and in combination, in the treatment of GAD. The results demonstrated that the greatest amount of positive changes was produced by cognitive-behavioural treatment and cognitive-behavioural treatment combined with medication.

Borkovec and Castello (1993: 611-619), compared the effectiveness of three treatments for GAD: Nondirective therapy, Applied Relaxation and Cognitive Behavioural Therapy. Effectiveness was based on clinicians' ratings of their clients' level of anxiety both before and after the different therapies. Although improvement was evident among all participants, those in the applied relaxation and cognitive-behavioural treatments showed superior gains. However, no p-values were provided, and there was no placebo group, so it is difficult to objectively evaluate these results.

## **2.11 The placebo effect**

Placebo is a substance with no active biological properties. In a controlled clinical trial, it is used as an inactive agent that plays the role of a standard of comparison for the substance or method to be tested and is indistinguishable from it (Swayne, 2000: 162).

There are a number of factors that contribute to the **placebo effect**. These include the

(1) nature of the intervention e.g. injections vs. pills, the use of hi-tech approaches (ultra sound), the colour of the medication or the unusual nature of the therapeutic encounter (homoeopathic consultation). (2) The nature of the therapist e.g. confidence, demeanour, empathy, warmth, reputation and prestige. (3) The time factor involved - the longer the consultation the better the placebo effect. (4) The patient, their trust in the therapist and their worldviews. (5) The nature of the complaint. (6) The therapeutic setting (Peters, 2001: 25).

The placebo effect dates back to Hippocrates who observed that certain gravely ill people seemed to recover through sheer “contentment”. Placebo accounts for much of the benefit from anti-depressants and all the benefit from antibiotics taken for viral infections, which are not affected by the drug (Grady, 2004: 10).

The placebo effect is powerful. Examples cited by Hawkins (2001: 72) include (1) the use of saline injection for acute pain, (2) the placebo component of anti-depressants being nearly twice as powerful as the pharmacological component, (3) and the 2.5 time greater death rate over a years follow up for post-myocardial infarction patients who took their prescribed placebo medicine irregularly as compared to those who took it regularly.

According to Benson and Friedman (1996: 194-195), the placebo is the aspect of treatment not attributable to specific pharmacologic or physiologic properties. They have proposed that the determinants of the placebo effect are a positive belief and

expectation on the part of the patient, a positive belief and a positive belief of expectation on the part of the physician, and a good relationship existing between both the patient and physician

## **2.12 Conclusion**

Pharmaceutical treatments available for GAD appear not to be maintaining long-term resolution of symptoms, with mainstream treatment being aimed largely at the biological level of symptom management. Whilst these mood-altering substances have no doubt saved lives or brought transient relief to some patients, they do not seem to provide long-term benefits (Pande et al., 2002: 533).

Homoeopathic treatment recognizes the complexity and individuality of the patient suffering from GAD so it is suitable for treatment of GAD. A clinical trial of the homoeopathic simillimum treatment of GAD has already been conducted (Bonne et al., 2003).

This study aims to extend knowledge regarding homoeopathy and the treatment of GAD.

## **CHAPTER THREE**

### **Materials and methods**

#### **3.1 Study design**

For the objectives of the research, see Chapter 1.2.

This clinical trial consisted of three groups; Group 1 (Homoeopathic simillimum), Group 2 (Psychological counselling) and Group 3 (Placebo). It was a double blind placebo controlled clinical trial, which included both quantitative and qualitative measures. This clinical trial was conducted at the Homoeopathic Day Clinic at the Durban Institute of Technology. These groups were then compared with each other in order to establish the difference a homoeopathic treatment has on GAD as compared to psychological counselling and to placebo in terms of the Hamilton Anxiety Rating Scale (refer Appendix F), the Beck Anxiety Inventory (refer Appendix G) and the Patient Perception Questionnaires (refer Appendix H).

#### **3.2 Recruitment**

##### **3.2.1 Advertising**

An advertisement (Appendix N) for this clinical trial was published on the notice boards of various institutions of higher learning, hospitals, health awareness clinics, libraries,

various malls, distributed in the form of pamphlets and also by verbal communication, in the Greater Durban area.

### **3.2.2 Selection Criteria**

#### **INCLUSION CRITERIA:**

1. Participants had to be male or female.
2. Participants had to be between the age of 18 and 60 years.
3. Diagnosis by the researcher according to the DSM IV (1994) criteria for Generalized Anxiety Disorder - 300.02. Participants who had been pre-diagnosed and who had a written confirmation of their diagnosis would also be accepted.

The diagnostic criteria was:

- A. Excessive anxiety and worry (apprehensive expectation), occurring more days than not for at least 6 months, about a number of events or activities (such as work or school performance).
- B. The person finds it difficult to control the worry.
- C. The anxiety and worry are associated with three (or more) of the following six symptoms ( with at least some symptoms present for more days for the

past 6 months):

- Restlessness or feeling keyed up or on edge;
  - Being easily fatigued;
  - Difficulty concentrating or mind going blank;
  - Irritability;
  - Muscle tension;
  - Sleep disturbance difficulty falling or staying asleep or restless;  
(unsatisfying sleep).
- D. The focus of the anxiety and worry is not confined to features of an AXIS I Disorder, e.g., the anxiety or worry is not about having a panic attack (as in Panic Disorder ), being embarrassed in public (as in Social Phobia), being contaminated (as in Obsessive Compulsive Disorder), being away from home or close relatives (as in Separation Anxiety Disorder), gaining weight (as in Anorexia Nervosa), having multiple physical complaints (as in Somatisation Disorder), or having serious illness(as in Hypochondriasis), and the anxiety and worry do not occur exclusively during Post-traumatic Stress Disorder.
- E. The anxiety, worry or physical symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.
- F The disturbance is not due to the direct physiological effects of

a substance (e.g. a drug of abuse, a medication) or a general medical condition (e.g., hyperthyroidism) and does not occur exclusively during a Mood Disorder, a Psychotic Disorder, or a Passive Developmental Disorder.

4. Participants had to be willing to not change their lifestyle and eating habits for the duration of the trial period.
5. They had to be literate to understand and fill in questionnaires (English or Zulu).
6. Participants had to be from the Greater Durban area with access to the Durban Institute of Technology (DIT) Homoeopathic Day Clinic.

**EXCLUSION CRITERIA:**

1. Any volunteer who was pregnant, lactating, undergoing any other form of treatment or medication for GAD.
2. Volunteers who were on other medication and or intervention for GAD and were not willing to stop this whilst in the study.

3. Volunteers suffering from any other psychological disorder e.g. Depression.

### **3.2.3 Sampling**

A total of 41 participants were selected for this study by means of convenience sampling and were each treated for a period of 4 weeks. 34 Participants completed this 4-week study.

Participation in the study was voluntary. Each participant had to read the study information sheet (refer Appendix A) and sign the consent form (refer Appendix B).

### **3.2.4 Randomization**

Participants were randomly divided into three groups (Simillimum, Psychological Counselling and Placebo). A randomization list was drawn up at the start of the study by the Homoeopathic Day Clinic Director, in which numbers 1-36 were listed and each number was randomly assigned to one of the following groups “Simillimum”, “Counselling” or “Placebo”. Participants were entered chronologically on the list, as they were included in the study (Refer Appendix I).

The homoeopharmaceutical technician at the Homoeopathic Day Clinic dispensed to each participant either the simillimum remedy or placebo powders or a referral letter or placebo powders only according to the list.

### **3.2.5 Protocol**

The three measurement tools were completed at each consultation i.e. three times each. On each occasion, participants received their relevant treatment. Neither the participant nor the researcher knew whether the participant had received simillimum or placebo and the researcher did not know which participants received psychological counselling as they were asked not to disclose that information to the researcher. Each participant had three consultations with the homoeopath that were 2 weeks apart. Those in the Psychological Counselling group had three consultations with the psychologist. Each psychological counselling consultation was in the same week after each homoeopathic consultation.

Each participant was in the study for 4 weeks. Medication was prescribed at the first two consultations with the homoeopath. Powders (numbered 1-3) were dispensed. The instructions were to take one powder every morning for three days.

The Simillimum group received homoeopathic simillimum powders only, the Psychological Counselling group received placebo powders and had Cognitive therapy combined with Behavioural therapy. The Placebo group received placebo powders only. Thus, all three groups received powders.

### **3.3 Ethical considerations**

GAD is not a life threatening condition. Informed consent (Appendix B), which they signed was obtained from all participants, each of whom was provided with a detailed information letter (Appendix A) pertaining to the study (risks, benefits, etc) followed by an additional explanation provided by the researcher. Participants who received the placebo were offered free treatment at the end of the study trial. Should it have been necessary, any participant who required additional urgent treatment for their anxiety would have been immediately excluded from the study and referred to a homoeopath and /or psychiatrist or psychologists. This however did not happen as none did require additional urgent treatment for their anxiety. Participants were also free to withdraw from the study without offering a reason.

### **3.4 Treatment**

#### **3.4.1 Preparation of experimental medicines**

1. All remedies utilized for the study were dispensed from the Homoeopathic Day Clinic dispensary.

2. Medicines comprised of individually wrapped (0,5g) lactose powders and granules, labelled by number (1-3).
3. The powders of both active and placebo groups contained approximately 10 white lactose granules. The lactose granules within the active powders (simillimum) were triple impregnated, at 1% v/v, with the relevant medicating potency in a 96% ethanol base. The medicated granules of homoeopathic simillimum were produced in accordance with the German Homoeopathic Pharmacopoeia (British Homoeopathic Association, 1991, as per Method number 10: pg. 39).
4. Impregnating potencies were produced by Natura Homoeopathic Laboratories, and produced using the Centesimal Scale of dilution.
5. The placebo granules were triple impregnated with 96% ethanol alone. Thus, the placebo and active medicaments were indistinguishable from each other in terms of colour, texture or taste between the medicated granules and the placebo granules.
6. The homoeopharmaceutical technician prepared the medication in the Homoeopathic Day Clinic dispensary, according to the prescription, although active powders were only dispensed if coincidental with the prescribed

randomization sheet.

7. The homoeopathic dispenser on duty handed out the appropriate treatment to participants without knowing whether it was active or placebo.

### **3.4.2 Homoeopathic simillimum only**

Homoeopathic simillimum treatment was based on Homoeopathic principles and a qualified Homoeopath at the Durban Institute of Technology Homoeopathic Day Clinic supervised each case to confirm an appropriate remedy was chosen.

The simillimum was selected based on the totality of physical, emotional and mental symptoms presented by the participant. These symptoms were elicited by taking an extensive case history.

The Radar computerized repertory (Radar, Version 9 - Archibel Belgium) was used to analyze these symptoms and to present remedy differentials. The symptom picture of the participant was matched with the symptom picture of a remedy selected from a Homoeopathic Materia Medica in order to give the most similar prescription.

Each participant had three (one initial, two follow up) consultations with the homoeopath at two weekly intervals. During each consultation the participant's subjective and objective responses to the treatment was assessed and recorded as per homoeopathic

case history. The remedy and potency could be changed during the course of the treatment as can be seen in Chapter Four (Table 4.41 Simillimum group treatment).

### **3.4.3 Psychological counselling and Placebo**

The intervention applied to this group was that of psychological counselling as well as placebo powders; the rationale being to standardise the effect of the variable of an orally administered 'medicine' on the condition.

Each participant had 3 (one initial, two follow up) consultations with the homoeopath, as well as 3 (one initial, two follow up) counselling sessions with the psychologist, at two weekly intervals. During each homoeopathic consultation the participant's subjective and objective responses to the treatment was assessed and recorded as per homoeopathic case history.

The psychologist was registered with the Health Professions Council of South Africa (HPCSA), and has been in practice since 1996.

### **3.4.4 Placebo only**

Each participant had 3 (one initial, two follow up) consultations with the homoeopath at two weekly intervals. During each consultation the participant's subjective and objective responses to the treatment was assessed and recorded as per homoeopathic case

history.

## **3.5 Consultation Procedures**

### **3.5.1 Consultations:**

#### **The First Consultation**

- 1 The purpose and nature of the study was fully disclosed to all participants accepted into the trial. Participants received a full explanation of the purpose of the study and the procedures. Participants were also informed that they might fall into one of the treatment groups and that there was a 33% possibility of falling in the placebo group.
- 2 Each participant then received a participant information letter and informed consent form to be signed (Appendix A, B).
- 3 Each participant was required to complete the Patient Perception Questionnaire (Appendix H), and the Hamilton Anxiety Rating Scale (HAM-A) and Beck Anxiety Inventory (BAI), (Appendix F, G), before commencement of the consultation. These were completed in the presence of the researcher. This was to establish a pre-intervention baseline level for each participant.
- 4 A thorough homoeopathic case history was then taken (Appendix C) and a physical examination performed (Appendix D).

- 5 A diagnosis of Generalized Anxiety Disorder was then confirmed.
  
- 6 Participants collected their first prescription at the clinic reception, where the dispenser on duty dispensed the medication to the respective groups according to the randomization sheet drawn up by the Homoeopathic Day Clinic Laboratory Technician. The second group received placebo powders and was then referred to a psychologist. They were asked not to disclose this information to the researcher at subsequent consultations.
  
- 7 Participants were instructed to take one powder once a day every morning for three days, starting the morning after the homoeopathic consultation. Participants simply opened one end of the sachets, poured the contents under their tongue, and let it dissolve. This was done daily a half an hour away from food and drinks. Caffeine and menthol had to be avoided whilst taking the remedy as these substances are purported to antidote homoeopathic remedies (Swayne, 2000: 12). Furthermore, participants were requested to not expose the medication to aromatic substances like camphor and peppermint, and not to expose it to sunlight (See Appendix E - How to take homoeopathic medication).

### Second Consultation

8. Each participant was required to complete the Patient Perception Questionnaire

(Appendix H), and the Hamilton Anxiety Rating Scale (HAM-A) and Beck Anxiety Inventory (BAI), (Appendix F, G), before commencement of the consultation.

These were completed in the presence of the researcher.

9. A thorough homoeopathic follow up case was then taken (Appendix O) and a physical examination performed (Appendix D).
  
10. Participants collected their second prescription at the clinic reception, where the dispenser on duty dispensed the medication in accordance to their number on the randomization sheet. The second group received placebo powders and was then referred to a psychologist. They were asked not to disclose this information to the researcher.
  
11. Participants were instructed to take the prescribed medication in the same was as Point 7 above.

### Third Consultation

12. Each participant was required to complete the Patient Perception Questionnaire (Appendix H), and the Hamilton Anxiety Rating Scale (HAM-A) and Beck Anxiety Inventory (BAI), (Appendix F, G), before commencement of the consultation. These were completed in the presence of the researcher.
  
13. A thorough homoeopathic follow up case was then taken (Appendix O) and a

physical examination performed (Appendix D).

14. There was no prescription in the final consultation; however, participants were told that should they need further homoeopathic treatment in the future they should contact the Homoeopathic Day Clinic.

### **3.5.2 Participant Compliance**

Unfortunately, there is no method to ensure 100% compliance in all aspects of the study and the researcher had to rely on each individual's commitment to the study. Every effort was made to ensure participants took medication as prescribed.

See figure 3.1 for a graphic summary of the study protocol and timeline.

**Week 1 - CONSULTATION 1**

Subject information letter

Informed consent form

HAM-A

BAI

PPQ

Case history

Physical examination

Prescription

Medication (week 1)

**(and Psychological Counselling for group 2)**

**Week 2**

**Week 3 - FOLLOW-UP 1**

HAM-A

BAI

PPQ

consultation

vital signs

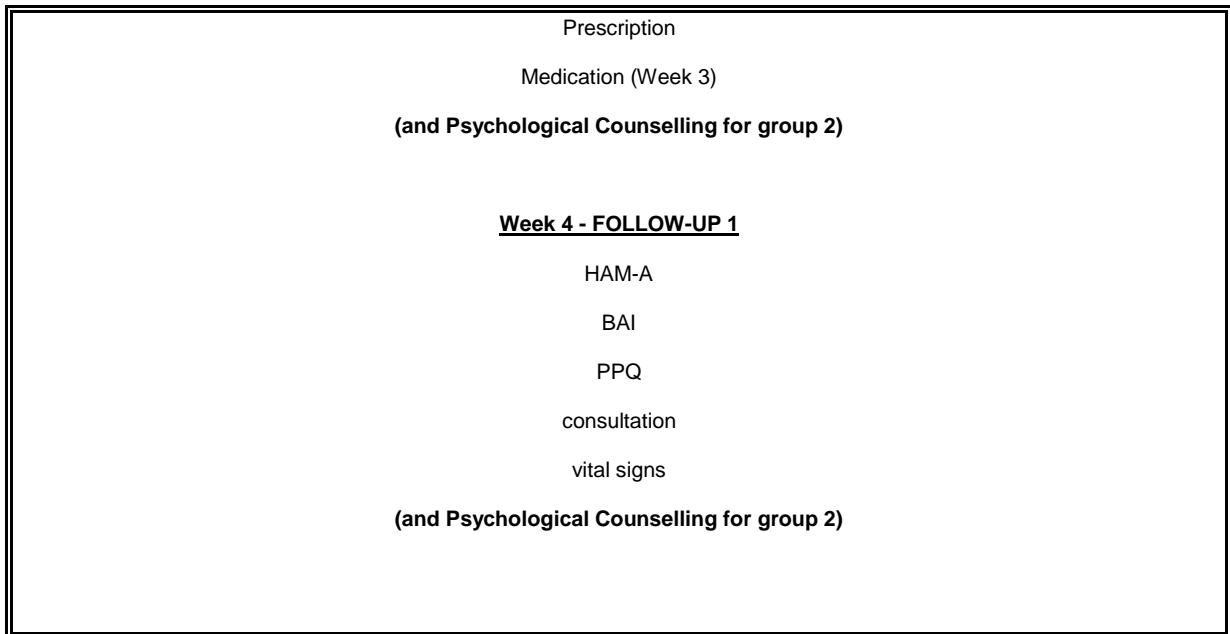


Figure 3.1 Summary of consultation time-line.

## **3.6 Data Analysis**

### **3.6.1 Statistical methods**

At the beginning of each of the three consultations the participants were asked to complete two anxiety scales (Appendix F and G) and the Patient Perception Questionnaire (Appendix H), before commencement of each treatment.

#### **Summary of groups used in statistical analysis**

Seven participants dropped out of the study trial. Therefore, statistical analysis was on the basis of 34 participants. Group 1 had 3 drop-outs and Group 2 had 4 drop-outs.

Group 1 contained 11 participants that completed the trial that made up the Simillimum

group. Group 2 contained 10 participants that completed the trial that made up the Psychological Counselling group. Group 3 contained 13 participants that completed the study trial that made up the Placebo group.

The sample size per group was ( $n_1=11$ ,  $n_2=10$ ,  $n_3=13$ ) therefore non-parametric methods (The Wilcoxon Signed Ranks and Kruskal-Wallis test) were used to analyze the data.

The severity of anxiety symptoms of each measurement data was evaluated using SPSS (Version 13.1) to statistically analyze the data.

### **3.6.1.1 Intra-Group Comparisons**

#### **3.6.1.1.1 Procedure one: Wilcoxon Signed Rank Test**

The purpose of this analysis was to determine whether there was any improvement within each of the three groups between the initial (first) consultation and second consultation, between second consultation and third (final) consultation and between initial and third consultation with respect to each variable of interest.

To do this, Wilcoxon's Signed Rank test was performed at the  $\alpha = 0.05$  level of significance.

(i) Hypothesis Testing:

$H_0$ : There is no improvement between consultations

$H_1$  : There is an improvement between consultations

$\alpha = 0.05$  level of significance.

(ii) Decision Rule two-tailed test:

For a two tailed test, the null hypothesis is rejected if  $p < \alpha$  where  $p$  is observed significance level or p-value.

Reject hypothesis if  $p < \alpha = 0.05$

Accept hypothesis if  $p > \alpha = 0.05$

Where  $p$  = reported p-value

### **3.6.2 Procedure two: Kruskal Wallis Test**

Group1, 2 and 3 were compared to each other with regards to the anxiety measurements (Appendix F, G, and H) using the Kruskal-Wallis non parametric Analysis of Variance (ANOVA) method. If a significant difference was found between any of the groups, then the Mann-Whitney unpaired test was to be used to determine between which pair the difference existed.

(i) Hypothesis testing:

In each test the null hypothesis  $H_0$ , states that there is no significant difference between the groups being compared at  $\alpha = 0.05$  level of significance. The alternative hypothesis  $H_1$ , states that at least two of the groups will differ significantly at the same level of significance.

(ii) Decision Rule:

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

### **3.6.3 Procedure three: Mann-Whitney Test**

The Mann-Whitney test was not applied because there were no significant statistical differences between groups according to the Kruskal Wallis test, therefore there was no need to determine between which pair of groups the significant difference lay with regards to the variables of the measurements in the study trial.

### **3.6.4 Procedure four: Comparison using Bar Charts**

Bar graphs were constructed to give a visual summary of the results obtained from

the comparison between Simillimum (Group1), Psychological Counselling (Group 2) and Placebo (Group3) at each consultation of each variable (Appendix F, G and H). The means of the totals of each variable was used. These bar graphs were constructed using SPSS for Windows, Version 13.1.

### **3.6.5 Procedure five: Demographic pie charts (Age and Gender) Distribution**

Pie charts were constructed to give a demographic analysis of age and gender distributions amongst participants. Data was obtained from case histories of participants.

### **3.6.6 Summary of remedies prescribed (Table 4.40)**

The summary of remedies prescribed table was constructed to give a brief summary of the remedies prescribed, the potencies and the frequency of prescription for each remedy.

Where x = number of times the remedy was prescribed in that particular group.

30 = 30 Centesimal potency

200 = 200 Centesimal potency

M = 1 Millesimal potency

10M = 10 Millesimal potency

30/200/M = means three powdered potencies (powder no.1 = 30CH, powder

no. 2 = 200CH and powder no. 3 = M).

**Statistical Package:**

The statistical analysis of data entry was conducted using the Statistical package for Social Sciences (SPSS for Windows , Version 13.1 software suite). This statistical software program is manufactured by SPSS Inc, 444N. Michigan Avenue, Chicago, Illinois, USA.

## CHAPTER FOUR

Group 1 = Simillimum Group

Group 2 = Psychological Counselling Group

Group 3 = Placebo Group

p-value : observed significance level (p value  $\leq$  0.05).

### **4.1 Introduction**

In this chapter, results obtained from statistical analysis of data collected from the three groups used in this study trial is discussed.

The tests were performed using the SPSS Programme (Version 13.1).

### **4.2 Criteria for the admissibility of the data**

- 1 The only data that was accepted for statistical analysis chapter was that obtained from this research study.
- 2 The only data used in the analysis was collected in the manner described in Chapter Three
- 3 Only data for participants who completed the research study was collected.
- 4 No data was excluded from statistical analysis.

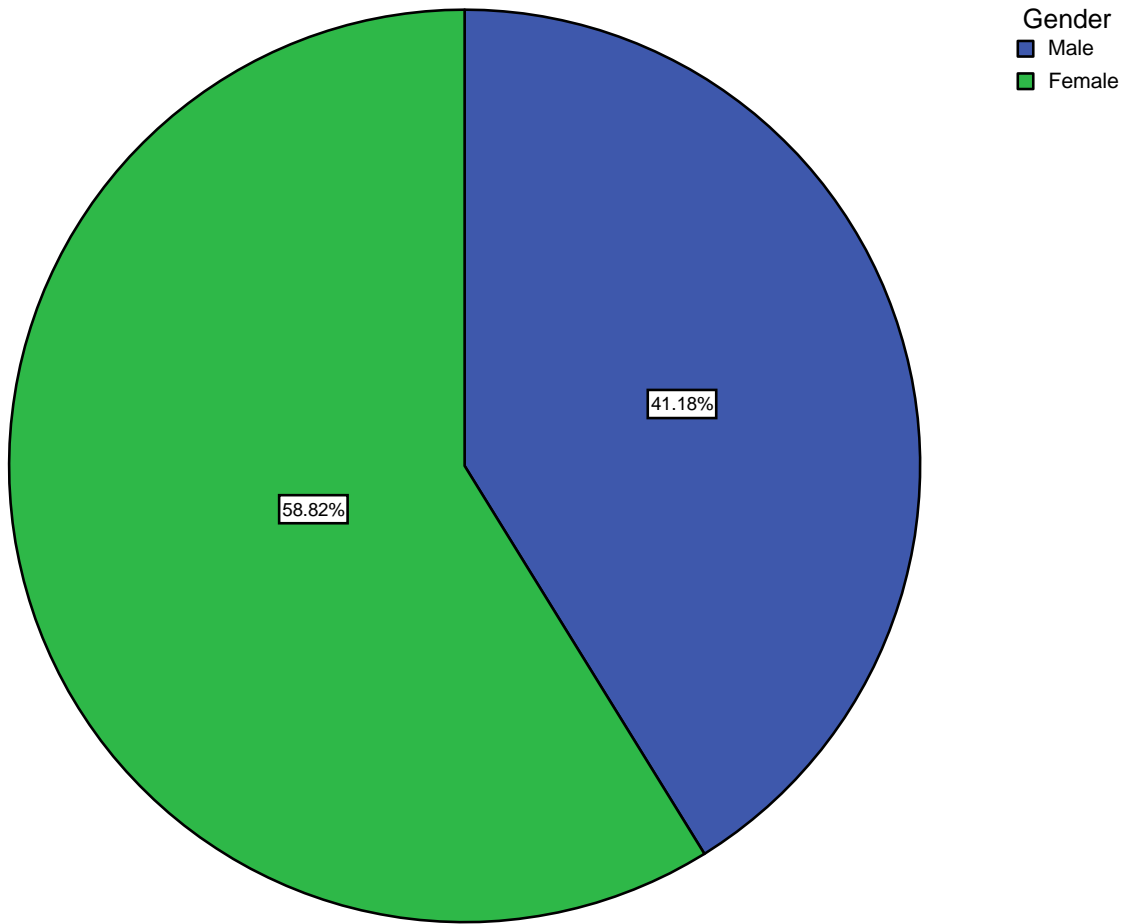
### **4.3 Assumptions**

The researcher assumes that:-

- a) Participants read and understood the subject information letter (Appendix A), and complied with the conditions stated therein, and
- b) Participants took their medication as prescribed.

At each follow up participants were asked if and how they took the medication in order to ensure the prescribed procedures were adhered to.

#### **4.4 Demographic Data of the Sample**



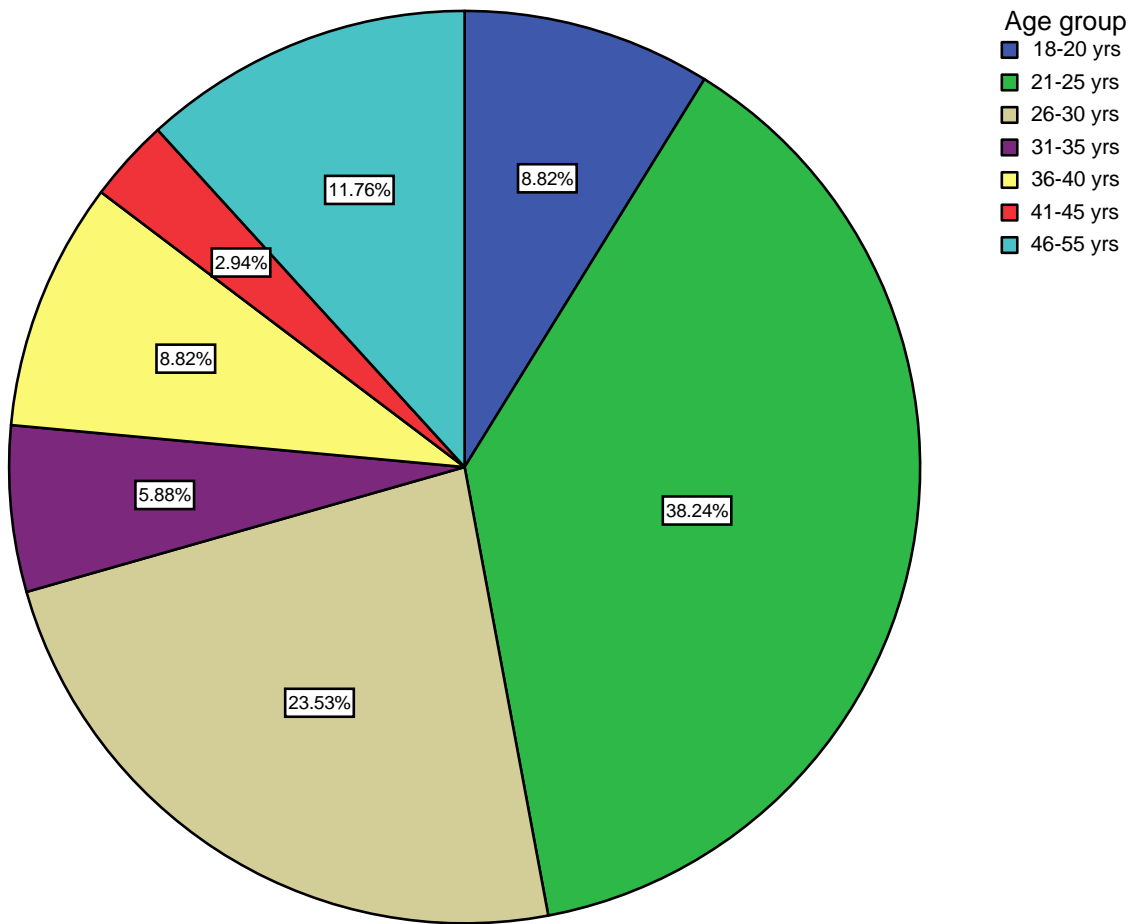
**Figure 4.1 Gender distributions of participants (%).**

Figure 4.1 shows the percentage of gender distribution of participants (%).

**Table 4.1 Gender distribution amongst participants in each group.**

		Gender	
		Male	Female
	Similimum	5	6
	Counselling	5	5
	Placebo	4	9

Table 4.1 shows the gender distribution amongst participants within each group.



**Figure 4.2 Age-group distributions of participants (%).**

Figure 4.2 shows the percentage of age-group distribution of participants (%).

**Table 4.2 Age-group distribution amongst participants in each group.**

		Age group						
		18-20 yrs	21-25 yrs	26-30 yrs	31-35 yrs	36-40 yrs	41-45	46-55
	Similimum		6	4	1			
	Counselling		3	2	1	2		2
	Placebo	3	4	2		1	1	2

Table 4.2 shows the age-group distribution amongst participants within each group.

## **4.5 Intra-group analysis using WILCOXON SIGNED RANK**

### **TEST**

#### **4.5.1 Hamilton Anxiety Rating Scale (HAM-A)**

##### **4.5.1.1 Simillimum Group**

**Aim:** The Wilcoxon Signed Rank Test was performed to determine if there was any significant statistical improvement within the Simillimum group, between first consultation and second consultation and between second consultation and third consultation and between the first consultation and the third consultation with respect to Hamilton Anxiety Scale, labeled as Hamilton Total 1, 2 and 3. The test was performed at the 0.05 level of significance.

**Table 4.3 Ranks according to HAM-A at each consultation (in the Simillimum**

group).

	Hamilton total - 2 - Hamilton total -1	Hamilton total - 3 - Hamilton total - 2	Hamilton total - 3 - Hamilton total - 1
Z	-2.137(a)	-.408(a)	-1.827(a)
<b>Asymp. Sig. (2-tailed)</b>	<b>.033</b>	.683	.068

Table 4.3 shows ranks according to HAM-A at each consultation in the Simillimum group.

a Based on positive ranks.

b Based on negative ranks.

c Wilcoxon Signed Ranks Test

See corresponding barcharts (Figure 4.3)

### **Results:-**

1. A test score of 0.33 indicates a significant statistical difference between the first consultation and the second consultation.
2. A test score of 0.683 indicates no significant statistical difference between the second consultation and the third consultation.
3. A test score of 0.068 indicates no significant statistical difference between the first consultation and the third consultation.

### **Conclusion:-**

There was a significant statistical difference in severity of anxiety between baseline and second consultation only, as measured by the Hamilton Anxiety Scale (HAM-A).

#### **4.5.1.2 Psychological Counselling Group**

**Aim:** The Wilcoxon Signed Rank Test was performed to determine if there was any significant statistical improvement within the Counselling group, between first consultation and second consultation and between second consultation and third consultation and between the first consultation and the third consultation with respect to Hamilton Anxiety Scale, labeled as Hamilton Total 1, 2 and 3. The test was performed at the 0.05 level of significance.

**Table 4.4 Ranks according to HAM-A at each consultation (in the Psychological Counselling group).**

	Hamilton total - 2 - Hamilton total - 1	Hamilton total - 3 - Hamilton total - 2	Hamilton total - 3 - Hamilton total - 1
Z	-2.666(a)	-2.521(a)	-2.666(a)
<b>Asymp. Sig. (2-tailed)</b>	<b>.008</b>	<b>.012</b>	<b>.008</b>

Table 4.4 shows ranks according to HAM-A at each consultation in the Psychological Counselling group group.

See corresponding barcharts (Figure 4.3)

**Results:-**

1. A test score of 0.008 indicates a significant statistical difference between the first consultation and the second consultation.
2. A test score of 0.012 indicates a significant statistical difference between the second consultation and the third consultation.
3. A test score of 0.008 indicates a significant statistical difference between the first consultation and the third consultation.

**Conclusion:-**

There was a significant statistical difference in severity of anxiety between all the consultations, as measured by the Hamilton Anxiety Scale (HAM-A).

#### 4.5.1.3 Placebo Group

**Aim:** The Wilcoxon Signed Rank Test was performed to determine if there was any significant statistical improvement within the Placebo group, between first consultation and second consultation and between second consultation and third consultation and between the first consultation and the third consultation with respect to Hamilton Anxiety Scale, labeled as Hamilton Total 1, 2 and 3. The test was performed at the 0.05 level of significance.

**Table 4.5 Ranks according to HAM-A at each consultation (in the Placebo group).**

	Hamilton total - 2 - Hamilton total - 1	Hamilton total - 3 - Hamilton total - 2	Hamilton total - 3 - Hamilton total - 1
Z	-2.826(a)	-2.040(a)	-2.983(a)
<b>Asymp. Sig. (2-tailed)</b>	<b>.005</b>	<b>.041</b>	<b>.003</b>

Table 4.5 shows ranks according to HAM-A at each consultation in the Placebo group.

a Based on positive ranks.

b Wilcoxon Signed Ranks Test

See corresponding barcharts (Figure 4.3)

## **Results:-**

1. A test score of 0.005 indicates a significant statistical difference between the first consultation and the second consultation.
2. A test score of 0.041 indicates a significant statistical difference between the second consultation and the third consultation.
3. A test score of 0.003 indicates a significant statistical difference between the first consultation and the third consultation.

## **Conclusion:-**

There was a significant statistical difference in severity of anxiety between all the consultations, as measured by Hamilton Anxiety Scale (HAM-A).

## **4.5.2 Beck Anxiety Inventory**

### **4.5.2.1 Simillimum Group**

**Aim:** The Wilcoxon Signed Rank Test was performed to determine if there was any significant statistical improvement within the Simillimum group, between first consultation and second consultation and between second consultation and third consultation and between the first consultation and the third consultation with respect to the Beck Anxiety Inventory, labeled as Beck Total 1, 2 and 3. The test was performed at the 0.05 level of significance.

**Table 4.6 Ranks according to BAI at each consultation (in the Simillimum group).**

	Beck total - 2 - Beck total - 1	Beck total - 3 - Beck total - 2	Beck total - 3 - Beck total - 1
Z	-1.988(a)	-1.402(b)	-1.428(a)
<b>Asymp. Sig. (2-tailed)</b>	<b>.047</b>	.161	.153

Table 4.6 shows ranks according to BAI at each consultation in the Simillimum group.

a Based on positive ranks.

b Based on negative ranks.

c Wilcoxon Signed Ranks Test

See corresponding Barchart (Figure 4.4)

**Results:-**

1. A test score of 0.047 indicates a significant statistical difference between the first consultation and the second consultation.
2. A test score of 0.161 indicates no significant statistical difference between the second consultation and the third consultation.

3. A test score of 0.153 indicates no significant statistical difference between the first consultation and the third consultation.

**Conclusion:-**

There was a significant statistical difference in severity of anxiety between baseline and second consultation only, as measured by measured by the Beck Anxiety Inventory (BAI).

**4.5.2.2 Psychological Counselling Group**

**Aim:** The Wilcoxon Signed Rank Test was performed to determine if there was any significant statistical improvement within the Counselling group, between first consultation and second consultation and between second consultation and third consultation and between the first consultation and the third consultation with respect to the Beck Anxiety Inventory, labeled as Beck Total 1, 2 and 3. The test was performed at the 0.05 level of significance.

**Table 4.7 Ranks according to BAI at each consultation (in the Psychological Counselling group).**

	Beck total - 2 - Beck total - 1	Beck total - 3 - Beck total - 2	Beck total - 3 - Beck total - 1
Z	-2.433(a)	-2.437(a)	-2.807(a)
Asymp. Sig. (2-tailed)	.015	.015	.005

Table 4.7 shows ranks according to BAI at each consultation in the Psychological Counselling group.

a Based on positive ranks.

b Wilcoxon Signed Ranks Test.

See corresponding Barchart (Figure 4.4)

### **Results:-**

1. A test score of 0.015 indicates a significant statistical difference between the first consultation and the second consultation.
2. A test score of 0.015 indicates a significant statistical difference between the second consultation and the third consultation.
3. A test score of 0.005 indicates a significant statistical difference between the first consultation and the third consultation.

### **Conclusion:-**

There was a significant statistical difference in severity of anxiety between all the consultations, as measured by the Beck Anxiety Inventory (BAI).

#### **4.5.2.3 Placebo Group**

**Aim:** The Wilcoxon Signed Rank Test was performed to determine if there was any significant statistical improvement within the Placebo group, between first consultation and second consultation and between second consultation and third consultation and between the first consultation and the third consultation with respect to Beck Anxiety Inventory, labeled as Beck Total 1, 2 and 3. The test was performed at the 0.05 level of significance.

**Table 4.8 Ranks according to BAI at each consultation (in the Placebo group).**

	Beck total - 2 - Beck total - 1	Beck total - 3 - Beck total - 2	Beck total - 3 - Beck total - 1
Z	-2.271(a)	-2.949(a)	-3.069(a)
<b>Asymp. Sig. (2-tailed)</b>	<b>.023</b>	<b>.003</b>	<b>.002</b>

Table 4.8 shows ranks according to BAI at each consultation in the Placebo group.

a Based on positive ranks.

b Wilcoxon Signed Ranks Test

See corresponding Barchart (Figure 4.4)

**Results:-**

1. A test score of 0.023 indicates a significant statistical difference between the first consultation and the second consultation.

2. A test score of 0.003 indicates a significant statistical difference between the second consultation and the third consultation.
3. A test score of 0.002 indicates a significant statistical difference between the first consultation and the third consultation.

### **Conclusion:-**

There was a significant statistical difference in severity of anxiety between all the consultations, as measured by the Beck Anxiety Inventory (BAI).

## **4.5.3 Patient Perception Questionnaire (PQ1 Total)**

### **4.5.3.1 Simillimum Group**

**Aim:** The Wilcoxon Signed Rank Test was performed to determine if there was any significant statistical improvement within the Simillimum Group, between first consultation and second consultation and between second consultation and third consultation and between the first consultation and the third consultation with respect to

the Patient Perception Questionnaire (PQ1 Total). The test was performed at the 0.05 level of significance.

**Table 4.9 Ranks according to PQ1 Total at each consultation (in the Simillimum group).**

	Perception total Q1 - 2 - Perception Q1total -1	Perception total Q1 - 3 - Perception total Q1 - 2	Perception total Q1 - 3 - Perception Q1total -1
Z	-1.779(a)	-1.250(a)	-2.136(a)
<b>Asymp. Sig. (2-tailed)</b>	.075	.211	<b>.033</b>

Table 4.9 shows ranks according to PQ1 Total at each consultation in the Simillimum group.

- a Based on positive ranks.
- b Based on negative ranks.
- c Wilcoxon Signed Ranks Test

See corresponding Barchart (Figure 4.5)

**Results:-**

1. A test score of 0.075 indicates no significant statistical difference between the first consultation and the second consultation.
2. A test score of 0.211 indicates no significant statistical difference between the second consultation and the third consultation.
3. A test score of 0.033 indicates a significant statistical difference between the first consultation and the third consultation.

### **Conclusion:-**

There was a significant statistical difference in severity of anxiety between baseline and the third consultations only, as measured by the Patient Perception Questionnaire (PQ1 Total).

#### **4.5.3.2 Psychological Counselling Group**

**Aim:** The Wilcoxon Signed Rank Test was performed to determine if there was any significant statistical improvement within the Counselling Group, between first consultation and second consultation and between second consultation and third consultation and between the first consultation and the third consultation with respect to the Patient Perception Questionnaire (PQ1 Total). The test was performed at the 0.05 level of significance.

**Table 4.10 Ranks according to PQ1 Total at each consultation (in the Psychological Counselling group).**

	Perception total Q1 - 2 - Perception Q1total -1	Perception total Q1 - 3 - Perception total Q1 - 2	Perception total Q1 - 3 - Perception Q1total -1
Z	-2.601(a)	-2.552(a)	-2.668(a)
<b>Asymp. Sig. (2-tailed)</b>	<b>.009</b>	<b>.011</b>	<b>.008</b>

Table 4.10 shows ranks according to PQ1 Total at each consultation in the Psychological Counselling group.

a Based on positive ranks.

b Wilcoxon Signed Ranks Test

See corresponding Barchart (Figure 4.5)

### **Results:-**

1. A test score of 0.009 indicates a significant statistical difference between the first consultation and the second consultation.
2. A test score of 0.011 indicates a significant statistical difference between the second consultation and the third consultation.
3. A test score of 0.008 indicates a significant statistical difference between the first consultation and the third consultation.

## **Conclusion:-**

There was a significant statistical difference in severity of anxiety between all the consultations, as measured by the Patient Perception Questionnaire (PQ1 Total).

### **4.5.3.3 Placebo Group**

**Aim:** The Wilcoxon Signed Rank Test was performed to determine if there was any significant statistical improvement within the Placebo Group, between first consultation and second consultation and between second consultation and third consultation and between the first consultation and the third consultation with respect to the Patient Perception Questionnaire (PQ1 Total). The test was performed at the 0.05 level of significance.

**Table 4.11 Ranks according to PQ1 Total at each consultation (in the Placebo group).**

	Perception total Q1 - 2 - Perception Q1total -1	Perception total Q1 - 3 - Perception total Q1 - 2	Perception total Q1 - 3 - Perception Q1total -1
Z	-2.836(a)	-2.719(a)	-3.063(a)
<b>Asymp. Sig. (2-tailed)</b>	<b>.005</b>	<b>.007</b>	<b>.002</b>

Table 4.11 shows ranks according to PQ1 Total at each consultation in the Placebo group.

- a Based on positive ranks.
- b Wilcoxon Signed Ranks Test

See corresponding Barchart (Figure 4.5)

### **Results:-**

1. A test score of 0.005 indicates a significant statistical difference between the initial consultation and the second consultation.
2. A test score of 0.007 indicates a significant statistical difference between the second consultation and the third consultation.
3. A test score of 0.002 indicates a significant statistical difference between the first consultation and the third consultation.

### **Conclusion:-**

There was a significant statistical difference in severity of anxiety between all the consultations, as measured by the Patient Perception Questionnaire (PQ1 Total).

## **4.5.4 Patient Perception Questionnaire (PQ2)**

### **4.5.4.1 Simillimum Group**

**Aim:** The Wilcoxon Signed Rank Test was performed to determine if there was any significant statistical improvement within the Simillimum Group, between first consultation and second consultation and between second consultation and third consultation and between the first consultation and the third consultation with respect to the Patient Perception Questionnaire (PQ2). The test was performed at the 0.05 level of significance.

**Table 4.12 Ranks according to PQ2 at each consultation (in the Simillimum group).**

	Sat/dis with GAD - 2 - Sat/dis with GAD - 1	Sat/dis with GAD - 3 - Sat/dis with GAD - 2	Sat/dis with GAD - 3 - Sat/dis with GAD - 1
Z	-2.232(a)	-1.414(a)	-2.388(a)
<b>Asymp. Sig. (2-tailed)</b>	<b>.026</b>	.157	<b>.017</b>

Table 4.12 shows ranks according to PQ2 at each consultation in the Simillimum group.

a Based on positive ranks.

- b The sum of negative ranks equals the sum of positive ranks.
- c Wilcoxon Signed Ranks Test

See corresponding Barchart (Figure 4.6)

### **Results:-**

1. A test score of 0.026 indicates a significant statistical difference between the first consultation and the second consultation.
2. A test score of 0.157 indicates no significant statistical difference between the second consultation and the third consultation.
3. A test score of 0.017 indicates a significant statistical difference between the first consultation and the third consultation.

### **Conclusion:-**

There was a significant statistical difference in severity of anxiety between the baseline and second consultation and between the baseline consultation and the third consultation, as measured by the Patient Perception Questionnaire (PQ2).

#### **4.5.4.2 Psychological Counselling Group**

**Aim:** The Wilcoxon Signed Rank Test was performed to determine if there was any significant statistical improvement within the Psychological Counselling Group, between

first consultation and second consultation and between second consultation and third consultation and between the first consultation and the third consultation with respect to the Patient Perception Questionnaire (PQ2). The test was performed at the 0.05 level of significance.

**Table 4.13 Ranks according to PQ2 at each consultation (in the Psychological Counselling group).**

	Sat/dis with GAD - 2 - Sat/dis with GAD - 1	Sat/dis with GAD - 3 - Sat/dis with GAD - 2	Sat/dis with GAD - 3 - Sat/dis with GAD - 1
Z	-1.976(a)	-.718(a)	-1.741(a)
<b>Asymp. Sig. (2-tailed)</b>	<b>.048</b>	.473	.082

Table 4.13 shows ranks according to PQ2 at each consultation in the Psychological Counselling group.

a Based on positive ranks.

b Wilcoxon Signed Ranks Test

See corresponding Barchart (Figure 4.6)

### **Results:-**

1. A test score of 0.048 indicates a significant statistical difference between the first consultation and the second consultation.
2. A test score of 0.473 indicates no significant statistical difference between the second consultation and the third consultation.
3. A test score of 0.082 indicates no significant statistical difference between the first consultation and the third consultation.

### **Conclusion:-**

There was a significant statistical difference in severity of anxiety between the baseline and second consultation, as measured by the Patient Perception Questionnaire (PQ2).

#### **4.5.4.3 Placebo Group**

**Aim:** The Wilcoxon Signed Rank Test was performed to determine if there was any significant statistical improvement within the Placebo Group, between first consultation and second consultation and between second consultation and third consultation and

between the first consultation and the third consultation with respect to the Patient Perception Questionnaire (PQ2). The test was performed at the 0.05 level of significance.

**Table 4.14 Ranks according to PQ2 at each consultation (in the Placebo group).**

	Sat/dis with GAD - 2 - Sat/dis with GAD - 1	Sat/dis with GAD - 3 - Sat/dis with GAD - 2	Sat/dis with GAD - 3 - Sat/dis with GAD - 1
Z	-2.434(a)	-2.226(a)	-2.971(a)
<b>Asymp. Sig. (2-tailed)</b>	<b>.015</b>	<b>.026</b>	<b>.003</b>

Table 4.14 shows ranks according to PQ2 at each consultation in the Placebo group.

a Based on positive ranks.

b Wilcoxon Signed Ranks Test

See corresponding Barchart (Figure 4.6)

## **Results:-**

1. A test score of 0.015 indicates a significant statistical difference between the first consultation and the second consultation.
2. A test score of 0.026 indicates a significant statistical difference between the second consultation and the third consultation.
3. A test score of 0.003 indicates a significant statistical difference between the first consultation and the third consultation.

## **Conclusion:-**

There was a significant statistical difference in severity of anxiety between all the consultations, as measured by the Patient Perception Questionnaire (PQ2).

## **4.5.5 Patient Perception Questionnaire (PQ3)**

### **4.5.5.1 Simillimum Group**

**Aim:** The Wilcoxon Signed Rank Test was performed to determine if there was any significant statistical improvement within the Simillimum Group, between first consultation and second consultation and between second consultation and third consultation and between the first consultation and the third consultation with respect to

the Patient Perception Questionnaire (PQ3). The test was performed at the 0.05 level of significance.

**Table 4.15 Ranks according to PQ3 at each consultation (in the simillimum group).**

	Interfere daily function - 2 - Interfere daily function - 1	Interfere daily function - 3 - Interfere daily function - 2	Interfere daily function - 3 - Interfere daily function - 1
Z	-2.058(a)	-.816(a)	-2.226(a)
<b>Asymp. Sig. (2-tailed)</b>	<b>.040</b>	.414	<b>.026</b>

Table 4.15 shows ranks according to PQ3 at each consultation (n the simillimum group).

- a Based on positive ranks.
- b The sum of negative ranks equals the sum of positive ranks.
- c Wilcoxon Signed Ranks Test

See corresponding Barchart (Figure 4.7)

### **Results:-**

1. A test score of 0.040 indicates a significant statistical difference between the first consultation and the second consultation.
2. A test score of 0.414 indicates no significant statistical difference between the second consultation and the third consultation.
3. A test score of 0.026 indicates a significant statistical difference between the first consultation and the third consultation.

### **Conclusion:-**

There was a significant statistical difference in severity of anxiety between the baseline and second consultation and between the baseline consultation and the third consultation, as measured by the Patient Perception Questionnaire (PQ3).

#### **4.5.5.2 Psychological Counselling Group**

**Aim:** The Wilcoxon Signed Rank Test was performed to determine if there was any significant statistical improvement within the Psychological Counselling Group, between first consultation and second consultation and between second consultation and third consultation and between the first consultation and the final consultation with respect to the Patient Perception Questionnaire (PQ3). The test was performed at the 0.05 level of

significance.

**Table 4.16 Ranks according to PQ3 at each consultation (in the Psychological Counselling group).**

	Interfere daily function - 2 - Interfere daily function - 1	Interfere daily function - 3 - Interfere daily function - 2	Interfere daily function - 3 - Interfere daily function - 1
Z	-1.341(a)	-2.271(a)	-2.030(a)
<b>Asymp. Sig. (2-tailed)</b>	.180	<b>.023</b>	<b>.042</b>

Table 4.16 shows ranks according to PQ3 at each consultation in the Psychological Counselling group.

a Based on positive ranks.

b Wilcoxon Signed Ranks Test

See corresponding Barcharts (Figure 4.7)

**Results:-**

1. A test score of 0.180 indicates no significant statistical difference between the first consultation and the second consultation.
2. A test score of 0.023 indicates a significant statistical difference between the second consultation and the third consultation.
3. A test score of 0.042 indicates a significant statistical difference between the first consultation and the third consultation.

### **Conclusion:-**

There was a significant statistical difference in severity of anxiety between the second consultation and the third consultation and between the baseline consultation and the third consultation, as measured by the Patient Perception Questionnaire (PQ3).

### **4.5.5.3 Placebo Group**

**Aim:** The Wilcoxon Signed Rank Test was performed to determine if there was any significant statistical improvement within the Placebo Group, between first consultation and second consultation and between second consultation and third consultation and between the first consultation and the third consultation with respect to the Patient Perception Questionnaire (PQ3). The test was performed at the 0.05 level of significance.

**Table 4.17 Ranks according to PQ3 at each consultation (in the Placebo group).**

	Interfere daily function - 2 - Interfere daily function - 1	Interfere daily function - 3 - Interfere daily function - 2	Interfere daily function - 3 - Interfere daily function - 1
Z	-2.496(a)	-2.530(a)	-3.002(a)
<b>Asymp. Sig. (2-tailed)</b>	<b>.013</b>	<b>.011</b>	<b>.003</b>

Table 4.17 shows ranks according to PQ3 at each consultation in the Placebo group.

a Based on positive ranks.

b Wilcoxon Signed Ranks Test

See corresponding Barchart (Figure 4.7)

**Results:-**

1. A test score of 0.013 indicates a significant statistical difference between the first consultation and the second consultation.

2. A test score of 0.011 indicates a significant statistical difference between the second consultation and the third consultation.
3. A test score of 0.003 indicates a significant statistical difference between the first consultation and the third consultation.

### **Conclusion:-**

There was a significant statistical difference in severity of anxiety between all consultations, as measured by the Patient Perception Questionnaire (PQ3).

## **4.5.6 Patient Perception Questionnaire (PQ4)**

### **4.5.6.1 Simillimum Group**

**Aim:** The Wilcoxon Signed Rank Test was performed to determine if there was any significant statistical improvement within the Simillimum Group, between first consultation and second consultation and between second consultation and third consultation and between the first consultation and the third consultation with respect to the Patient Perception Questionnaire (PQ4). The test was performed at the 0.05 level of significance.

**Table 4.18 Ranks according to PQ4 at each consultation (in the Simillimum group).**

	Noticibility to others - 2 - Noticibility to others - 1	Noticibility to others - 3 - Noticibility to others - 2	Noticibility to others - 3 - Noticibility to others - 1
Z	-1.709(a)	.000(b)	-1.549(a)
<b>Asymp. Sig. (2-tailed)</b>	.088	1.000	.121

Table 4.18 shows ranks according to PQ4 at each consultation in the Simillimum group.

a Based on positive ranks.

b The sum of negative ranks equals the sum of positive ranks.

c Wilcoxon Signed Ranks Test

See corresponding Barcharts (Figure 4.8)

**Results:-**

1. A test score of 0.088 indicates no significant statistical difference between the first consultation and the second consultation.

2. A test score of 1.000 indicates no significant statistical difference between the second consultation and the third consultation.
3. A test score of 0.121 indicates no significant statistical difference between the first consultation and the third consultation.

**Conclusion:-**

The test indicates no significant statistical difference in severity of anxiety between all the consultations, as measured by the Patient Perception Questionnaire (PQ4).

**4.5.6.2 Psychological Counselling Group**

**Aim:** The Wilcoxon Signed Rank Test was performed to determine if there was any significant statistical improvement within the Psychological Counselling Group, between first consultation and second consultation and between second consultation and third consultation and between the first consultation and the third consultation with respect to the Patient Perception Questionnaire (PQ4). The test was performed at the 0.05 level of significance.

**Table 4.19 Ranks according to PQ4 at each consultation (in the Psychological Counselling group).**

	Noticibility to others - 2 - Noticibility to others - 1	Noticibility to others - 3 - Noticibility to others - 2	Noticibility to others - 3 - Noticibility to others - 1
Z	-2.395(a)	-1.027(a)	-2.521(a)
<b>Asymp. Sig. (2-tailed)</b>	<b>.017</b>	.305	<b>.012</b>

Table 4.19 shows ranks according to PQ4 at each consultation in the Psychological Counselling group.

a Based on positive ranks.

b Wilcoxon Signed Ranks Test

See corresponding Barchart (Figure 4.8)

**Results:-**

1. A test score of 0.017 indicates a significant statistical difference between the first consultation and the second consultation.
2. A test score of 1.305 indicates no significant statistical difference between the second consultation and the third consultation.

3. A test score of 0.012 indicates a significant statistical difference between the first consultation and the third consultation.

### **Conclusion:-**

There was a significant statistical difference in severity of anxiety between the baseline and second consultation and between the baseline consultation and the third consultation, as measured by the Patient Perception Questionnaire (PQ4).

### **4.5.6.3 Placebo Group**

**Aim:** The Wilcoxon Signed Rank Test was performed to determine if there was any significant statistical improvement within the Placebo Group, between first consultation and second consultation and between second consultation and third consultation and between the first consultation and the third consultation with respect to the Patient Perception Questionnaire (PQ4). The test was performed at the 0.05 level of significance.

**Table 4.20 Ranks according to PQ4 at each consultation (in the Placebo group).**

	Noticibility to others - 2 - Noticibility to others - 1	Noticibility to others - 3 - Noticibility to others - 2	Noticibility to others - 3 - Noticibility to others - 1
Z	-.791(a)	-1.000(a)	-1.137(a)
<b>Asymp. Sig. (2-tailed)</b>	.429	.317	.256

Table 4.20 shows ranks according to PQ4 at each consultation in the Placebo group.

a Based on positive ranks.

b Wilcoxon Signed Ranks Test

See corresponding Barchart (Figure 4.8)

### **Results:-**

1. A test score of 0.429 indicates no significant statistical difference between the first consultation and the second consultation.
2. A test score of 0.317 indicates no significant statistical difference between the second consultation and the third consultation.
3. A test score of 0.256 indicates no significant statistical difference between the first consultation and the third consultation.

### **Conclusion:-**

There was no significant statistical difference in severity of anxiety between all the consultations, as measured by the Patient Perception Questionnaire (PQ4).

## **4.6 Inter-group Analysis using the Kruskal Wallis test**

**Aim:** The Kruskal Wallis non-parametric analysis of variance (ANOVA method) Test was performed to determine if there was any significant statistical improvement between any of the Groups. Group 1, 2 and 3 were compared to each other with respect to the Hamilton Anxiety Rating Scale (Appendix F), the Beck Anxiety Inventory (Appendix G) and the Patient Perception Questionnaire (Appendix H). The test was performed at the 0.05 level of significance.

**Results:-**

**Table 4.21 p-values of each group at each consultation as measured by HAM-A, BAI and PPQ.**

		<b><u>MEAN</u></b>	<b><u>MEAN</u></b>	<b><u>MEAN</u></b>		
<b>Scale</b>	<b>Consultation</b>	<b>Simillimum Group</b>	<b>Counsellin g Group</b>	<b>Placebo Group</b>	<b>P- Value</b>	<b>Conclusion</b>
HAM-A 1	<b>1</b>	12.64	21.80	18.31	0.101	<b>No difference</b>
HAM-A 1	<b>2</b>	13.00	18.45	20.58	0.166	<b>No difference</b>
HAM-A 1	<b>3</b>	17.09	14.94	18.35	0.717	<b>No difference</b>
BAI-1	<b>1</b>	18.41	14.00	18.31	0.499	<b>No difference</b>
BAI-1	<b>2</b>	17.27	15.40	19.31	0.644	<b>No difference</b>
BAI-1	<b>3</b>	22.64	13.00	16.62	0.078	<b>No difference</b>
PQ1Tot	<b>1</b>	13.32	21.75	17.77	0.150	<b>No difference</b>
PQ1Tot	<b>2</b>	15.45	17.45	19.27	0.643	<b>No difference</b>
PQ1Tot	<b>3</b>	18.82	13.93	19.12	0.402	<b>No difference</b>
PQ2	<b>1</b>	15.09	21.50	16.46	0.259	<b>No difference</b>

PQ2	2	15.95	17.67	18.69	0.774	No difference
PQ2	3	17.23	19.05	16.54	0.819	No difference
PQ3	1	17.86	18.75	16.23	0.815	No difference
PQ3	2	15.68	17.40	19.12	0.683	No difference
PQ3	3	18.91	14.70	18.46	0.534	No difference
PQ4	1	16.45	22.55	14.50	0.128	No difference
PQ4	2	16.91	16.15	19.04	0.740	No difference
PQ4	3	19.50	13.95	18.54	0.339	No difference

Table 4.21 shows p-values of each group at each consultation as measured by HAM-A, BAI and PPQ.

### **Conclusion:-**

The test indicates no significant statistical difference between the groups in the variables of anxiety at any of the three consultations as measured by the Hamilton Anxiety Rating Scale (Appendix F), the Beck Anxiety Inventory (Appendix G) and the Patient Perception Questionnaire (Appendix H).

## **4.7 MANN WHITNEY-U-TEST**

The Mann Whitney Test was not performed because the Kruskal Wallis showed no

significant statistical difference between the groups in the variables of anxiety at any of the consultations.

## **4.8 BARCHARTS**

**Aim:-** The Bar-charts were constructed to give a visual summary and representation of the results obtained from comparison between Group 1, 2 and 3, as measured by the Hamilton Anxiety Rating Scale (Appendix F), the Beck Anxiety Inventory (Appendix G) and the Patient Perception Questionnaire (Appendix H) at each consultation. The means of the totals of each consultation were used.

**Results:-**

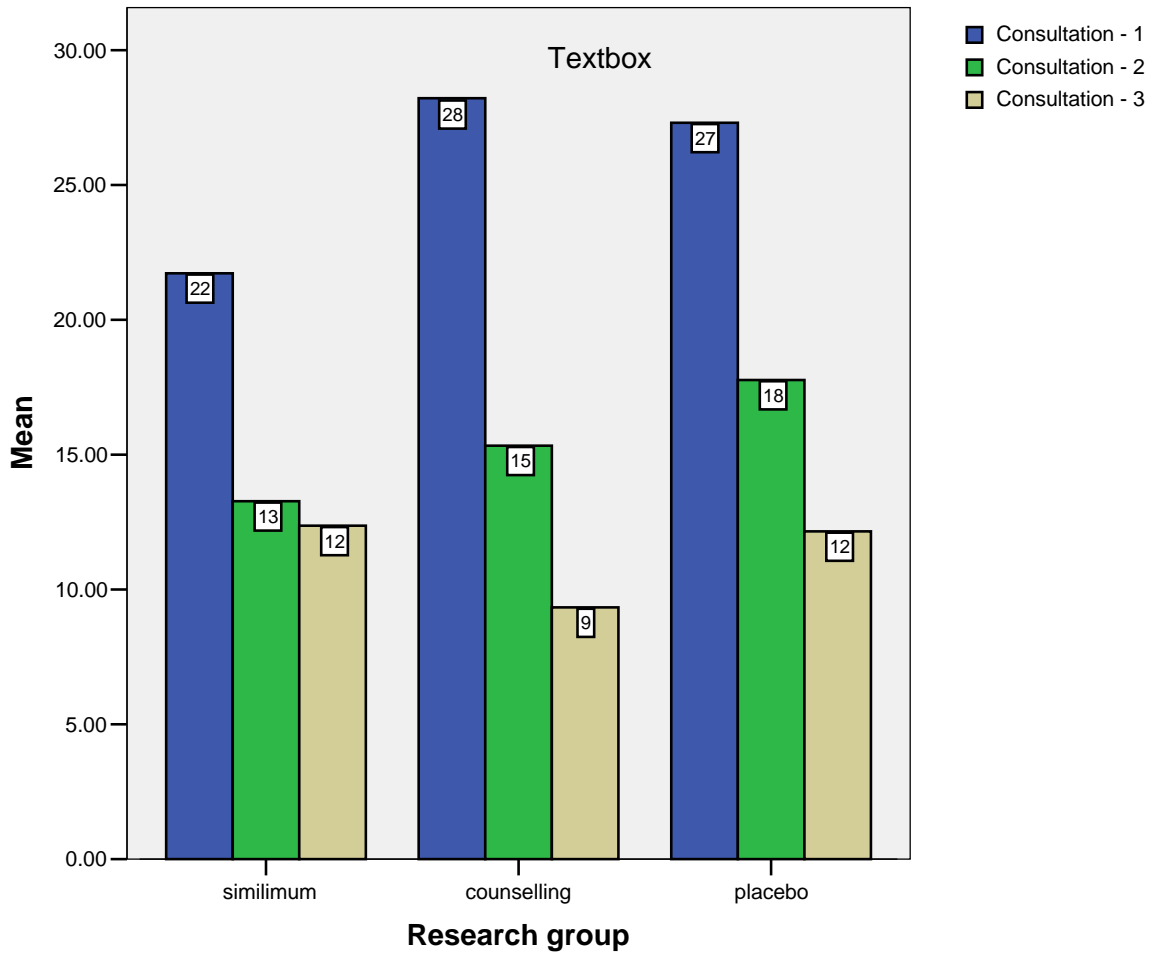


Figure 4.3 shows the mean scores per group at each consultation as measured by HAM-A. A reduction in mean scores indicates an improvement in anxiety symptoms

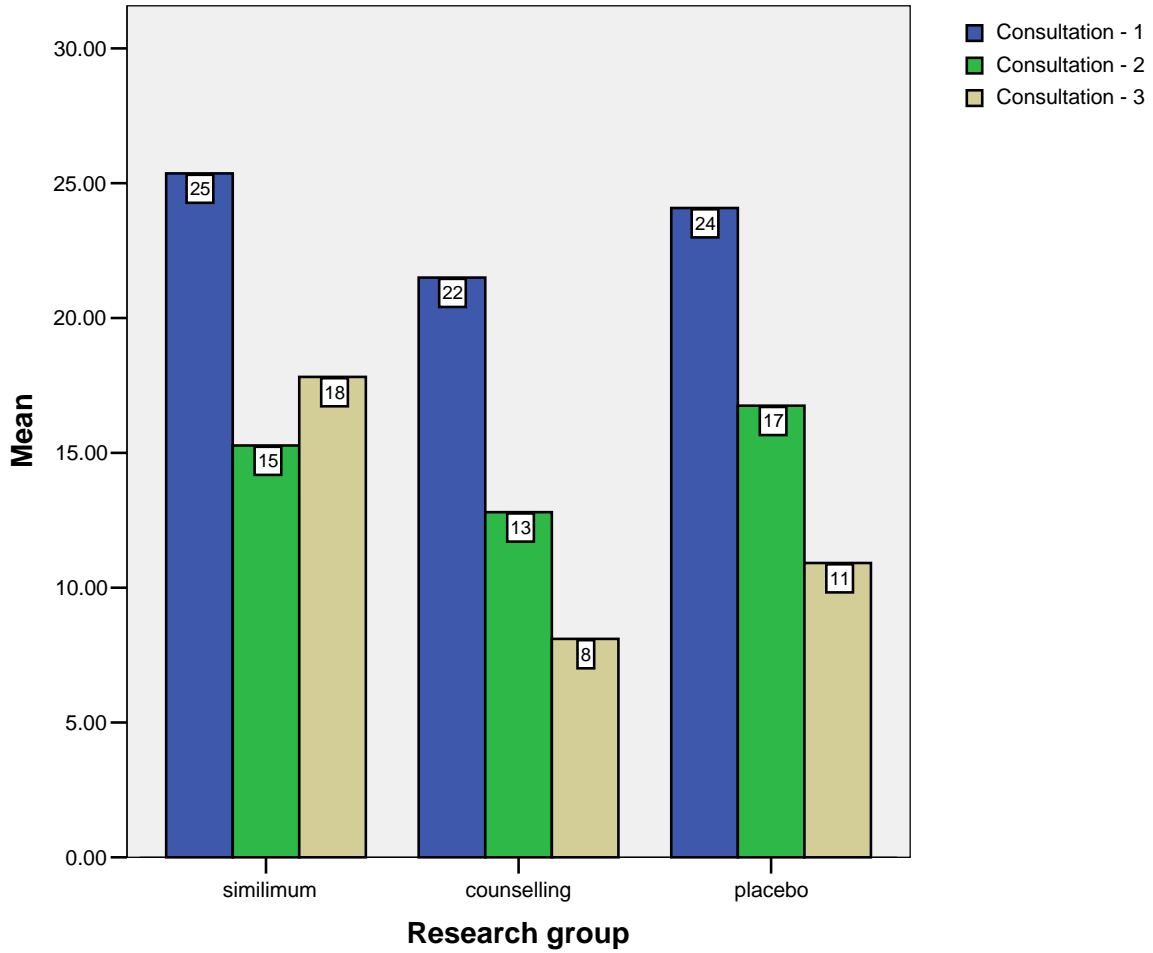


Figure 4.4 shows the mean scores per group at each consultation as measured by BAI. A reduction in mean scores indicates an improvement in anxiety symptoms.

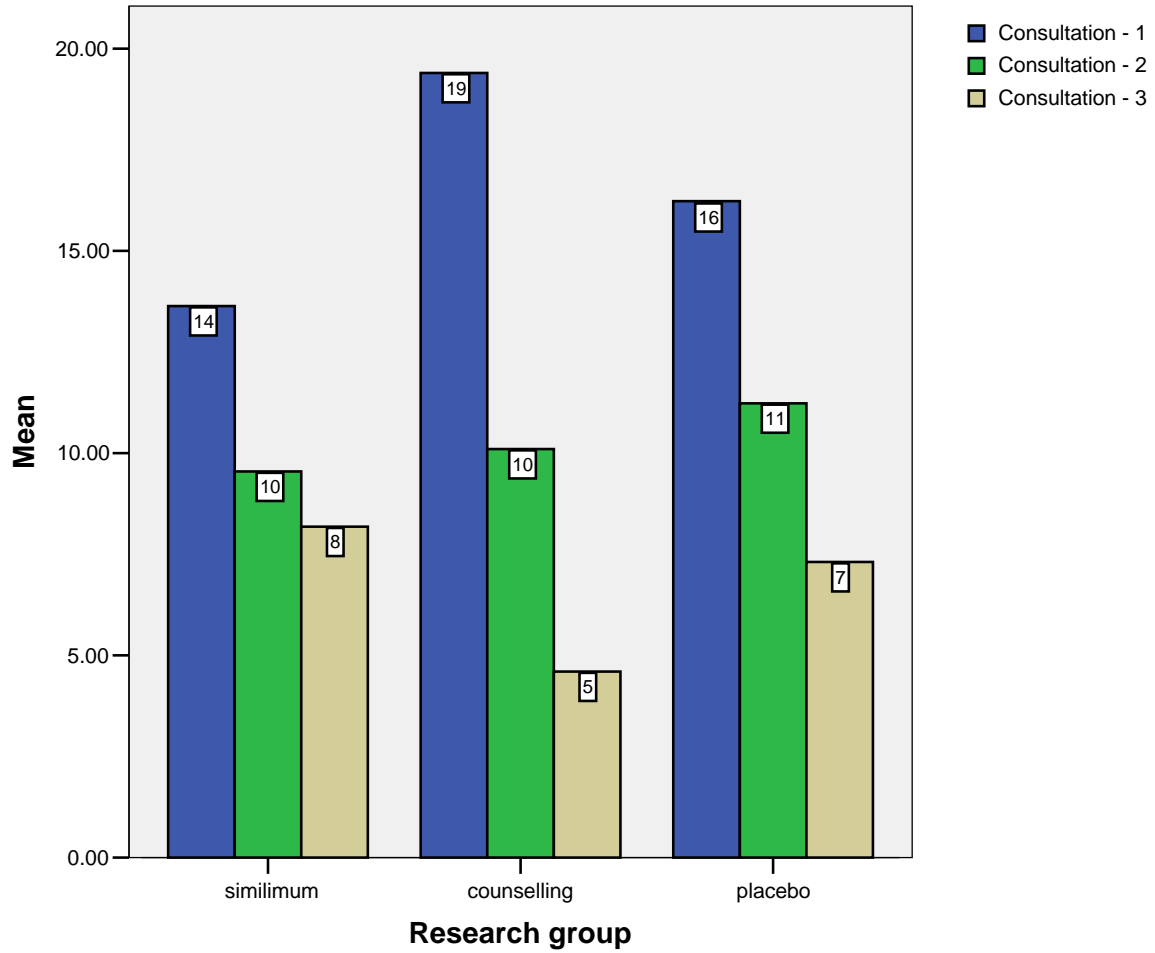


Figure 4.5 shows the mean scores per group at each consultation as measured by PQ1 Total. A reduction in mean scores indicates an improvement in anxiety symptoms.

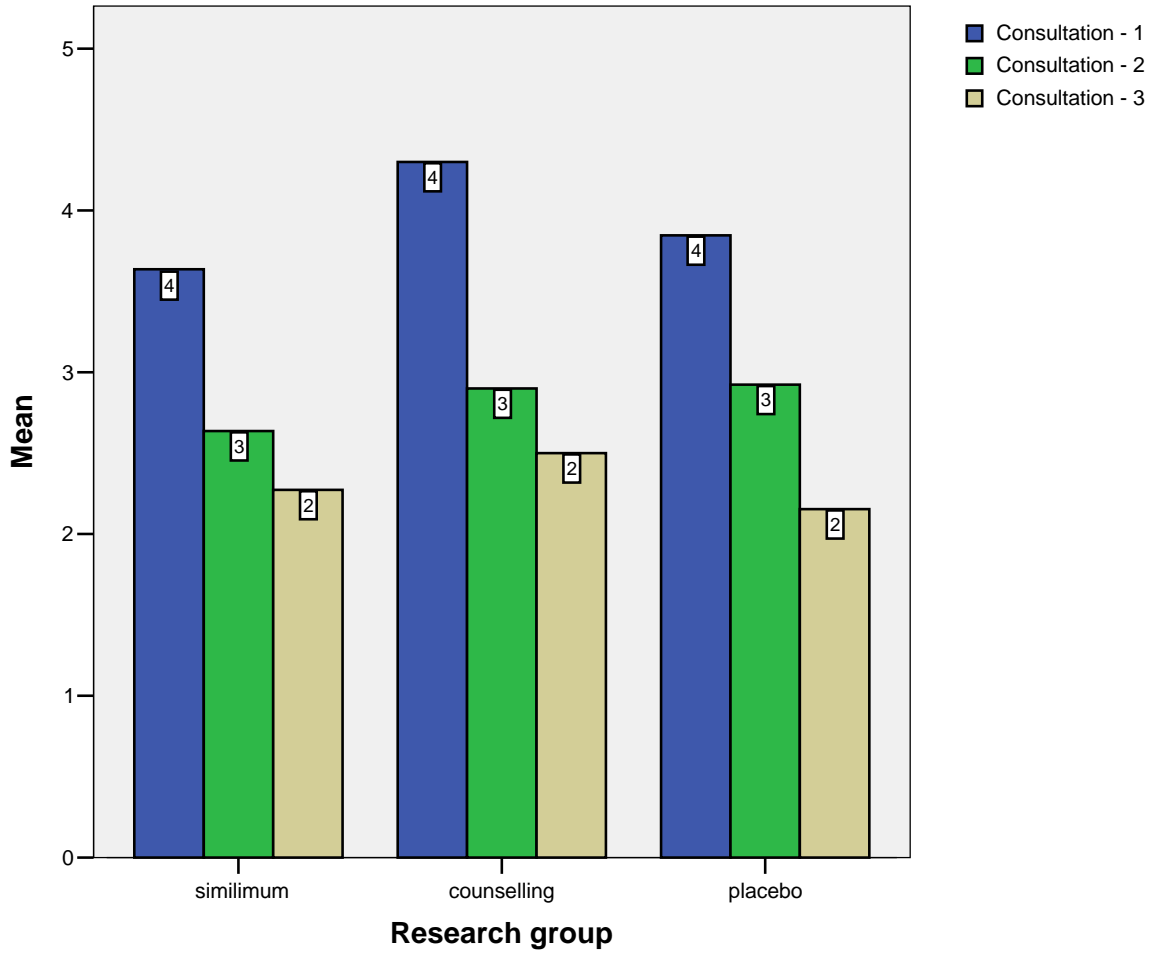


Figure 4.6 shows the mean scores per group at each consultation as measured by PQ2. A reduction in mean scores indicates an improvement in anxiety symptoms.

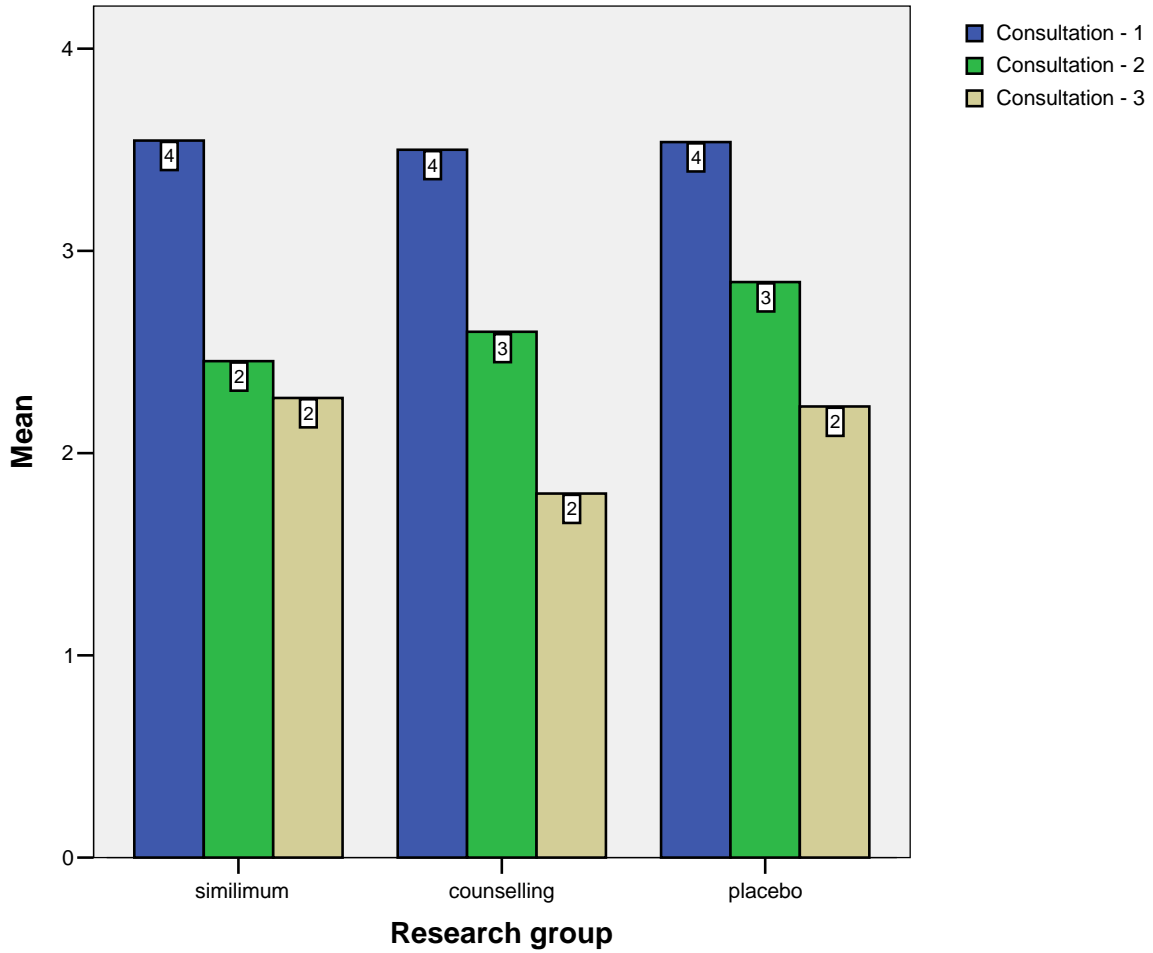


Figure 4.7 shows the mean scores per group at each consultation as measured by PQ3. A reduction in mean scores indicates an improvement in anxiety symptoms.

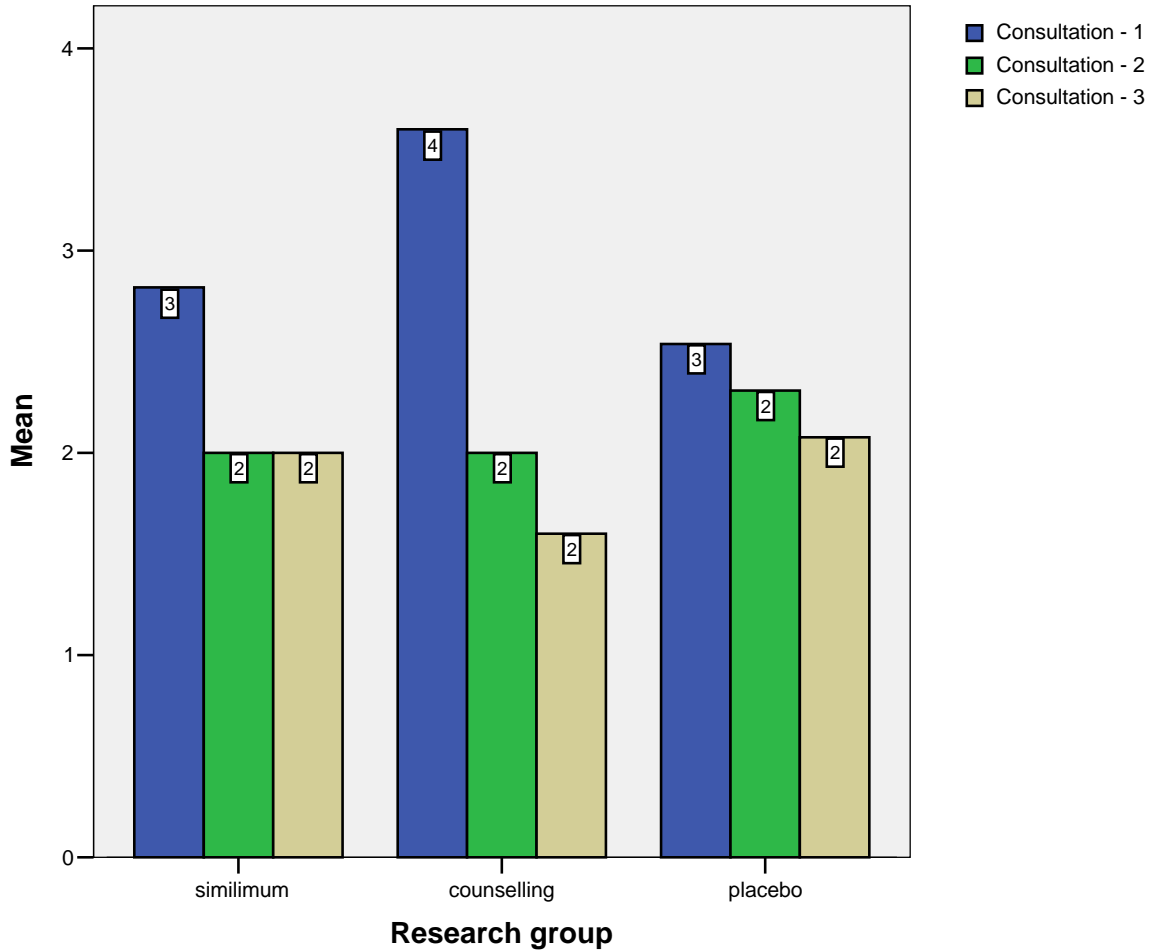


Figure 4.8 shows the mean scores per group at each consultation as measured by PQ4. A reduction in mean scores indicates an improvement in anxiety symptoms.

**Conclusion:-**

There was a decrease in the severity of anxiety symptoms from the initial consultation to the final consultation in all three groups as measured by Hamilton Anxiety Rating Scale (Appendix F), the Beck Anxiety Inventory (Appendix G) and the Patient Perception Questionnaire (Appendix H). However; the improvement in each of the groups did not

differ significantly from each other.

## **4.9 Frequency Tables**

### **Aim:-**

The descriptive mean tables were constructed to give a summary comparison for each group of the results obtained from the descriptive statistics of the total means for each group at each consultation.

### **4.9.1 Results - Group 1:**

**Table 4.22 Descriptive Statistics - Group 1 as measured by HAM-A.**

	N	Minimum	Maximum	Mean	Std. Deviation
Hamilton total - 1	11	6.00	32.00	21.7273	8.49813
Hamilton total - 2	11	3.00	42.00	13.2727	10.73397
Hamilton total - 3	11	.00	41.00	12.3636	11.54359
Valid N (listwise)	11				

Table 4.22 shows descriptive statistics - Group 1 as measured by HAM-A.

**Table 4.23 Descriptive Statistics - Group 1 as measured by BAI.**

	N	Minimum	Maximum	Mean	Std. Deviation
Beck total - 1	11	14.00	45.00	25.3636	10.09230
Beck total - 2	11	3.00	34.00	15.2727	9.56129
Beck total - 3	11	3.00	35.00	17.8182	11.14287
Valid N (listwise)	11				

Table 4.23 shows descriptive Statistics - Group 1 as measured by BAI.

**Table 4.24 Descriptive Statistics - Group 1 as measured by PQ1 Total.**

	N	Minimum	Maximum	Mean	Std. Deviation
Perception Q1total -1	11	5.00	23.00	13.6364	5.57266
Perception total Q1 - 2	11	2.00	23.00	9.5455	5.98938
Perception total Q1 - 3	11	.00	22.00	8.1818	7.11081
Valid N (listwise)	11				

Table 4.24 shows descriptive Statistics - Group 1 as measured by PQ1 Total.

**Table 4.25 Descriptive Statistics - Group 1 as measured by PQ2.**

	N	Minimum	Maximum	Mean	Std. Deviation
Sat/dis with GAD - 1	11	1	5	3.64	1.286
Sat/dis with GAD - 2	11	1.00	5.00	2.6364	1.28629
Sat/dis with GAD - 3	11	1.00	5.00	2.2727	1.27208
Valid N (listwise)	11				

Table 4.25 shows descriptive Statistics - Group 1 as measured by PQ2.

**Table 4.26 Descriptive Statistics - Group 1 as measured by PQ3.**

	N	Minimum	Maximum	Mean	Std. Deviation
Interfere daily function - 1	11	1	5	3.55	1.440
Interfere daily function - 2	11	1.00	5.00	2.4545	1.29334
Interfere daily function - 3	11	1.00	4.00	2.2727	1.19087
Valid N (listwise)	11				

Table 4.26 shows descriptive Statistics - Group 1 as measured by PQ3.

#### **Table 4.27 Descriptive Statistics - Group 1 as measured by PQ4**

	N	Minimum	Maximum	Mean	Std. Deviation
Noticibility to others - 1	11	1	5	2.82	1.401
Noticibility to others - 2	11	1.00	3.00	2.0000	.63246
Noticibility to others - 3	11	1.00	3.00	2.0000	.89443
Valid N (listwise)	11				

Table 4.27 shows descriptive Statistics - Group 1 as measured by PQ4

#### **4.9.2 Results - Group 2:**

#### **Table 4.28 Descriptive Statistics - Group 2 as measured by HAM-A.**

	N	Minimum	Maximum	Mean	Std. Deviation
Hamilton total - 1	10	15.00	45.00	29.9000	9.70052
Hamilton total - 2	10	4.00	29.00	15.4000	6.78561
Hamilton total - 3	9	.00	29.00	9.3333	7.88987
Valid N (listwise)	9				

Table 4.28 shows descriptive Statistics - Group 2 as measured by HAM-A.

#### **Table 4.29 Descriptive Statistics - Group 2 as measured by BAI.**

	N	Minimum	Maximum	Mean	Std. Deviation
Beck total - 1	10	12.00	46.00	21.5000	10.38428
Beck total - 2	10	5.00	26.00	12.8000	6.79542
Beck total - 3	10	.00	30.00	8.1000	8.56933
Valid N (listwise)	9				

Table 4.29 shows descriptive Statistics - Group 2 as measured by BAI.

**Table 4.30 Descriptive Statistics - Group 2 as measured by PQ1 Total.**

	N	Minimum	Maximum	Mean	Std. Deviation
Perception Q1total -1	10	7.00	28.00	19.4000	7.61869
Perception total Q1 - 2	10	2.00	17.00	10.1000	5.36346
Perception total Q1 - 3	10	.00	12.00	4.6000	3.94968
Valid N (listwise)	9				

Table 4.30 shows descriptive Statistics - Group 2 as measured by PQ1 Total.

**Table 4.31 Descriptive Statistics - Group 2 as measured by PQ2.**

	N	Minimum	Maximum	Mean	Std. Deviation
Sat/dis with GAD - 1	10	1	5	4.30	1.337
Sat/dis with GAD - 2	10	1.00	5.00	2.9000	1.10050
Sat/dis with GAD - 3	10	1.00	5.00	2.5000	1.26930
Valid N (listwise)	9				

Table 4.31 shows descriptive Statistics - Group 2 as measured by PQ2.

**Table 4.32 Descriptive Statistics - Group 2 as measured by PQ3.**

	N	Minimum	Maximum	Mean	Std. Deviation
Interfere daily function - 1	10	1	5	3.50	1.841
Interfere daily function - 2	10	1.00	4.00	2.6000	.96609
Interfere daily function - 3	10	1.00	4.00	1.8000	1.13529
Valid N (listwise)	9				

Table 4.32 shows descriptive Statistics - Group 2 as measured by PQ3.

**Table 4.33 Descriptive Statistics - Group 2 as measured by PQ4.**

	N	Minimum	Maximum	Mean	Std. Deviation
Noticibility to others - 1	10	2	5	3.60	1.075
Noticibility to others - 2	10	1.00	4.00	2.0000	.94281
Noticibility to others - 3	10	1.00	5.00	1.6000	1.26491
Valid N (listwise)	9				

Table 4.33 shows descriptive Statistics - Group 2 as measured by PQ4.

**4.9.3 Results - Group 3:**

**Table 4.34 Descriptive Statistics - Group 3 as measured by HAM-A.**

	N	Minimum	Maximum	Mean	Std. Deviation
Hamilton total - 1	13	12.00	39.00	27.3077	6.75012
Hamilton total - 2	13	6.00	35.00	17.7692	8.45728
Hamilton total - 3	13	1.00	24.00	12.1538	8.11219
Valid N (listwise)	12				

Table 4.34 shows descriptive Statistics - Group 3 as measured by HAM-A.

**Table 4.35 Descriptive Statistics - Group 3 as measured by BAI.**

	N	Minimum	Maximum	Mean	Std. Deviation
Beck total - 1	12	9.00	41.00	24.0833	9.51036
Beck total - 2	13	3.00	38.00	18.1538	12.19184
Beck total - 3	13	.00	24.00	11.3077	8.63505
Valid N (listwise)	12				

Table 4.35 shows descriptive Statistics - Group 3 as measured by BAI.

**Table 4.36 Descriptive Statistics - Group 3 as measured by PQ1 Total.**

	N	Minimum	Maximum	Mean	Std. Deviation
Perception Q1total -1	13	9.00	26.00	16.2308	4.95234
Perception total Q1 - 2	13	6.00	19.00	11.2308	4.71087
Perception total Q1 - 3	13	1.00	15.00	7.3077	5.42194
Valid N (listwise)	12				

Table 4.36 shows descriptive Statistics - Group 3 as measured by PQ1 Total.

**Table 4.37 Descriptive Statistics - Group 3 as measured by PQ2.**

	N	Minimum	Maximum	Mean	Std. Deviation
Sat/dis with GAD - 1	13	1	5	3.85	1.144
Sat/dis with GAD - 2	13	1.00	5.00	2.9231	1.25576
Sat/dis with GAD - 3	13	1.00	4.00	2.1538	1.14354
Valid N (listwise)	12				

Table 4.37 shows descriptive Statistics - Group 3 as measured by PQ2.

**Table 4.38 Descriptive Statistics – Group 3 as measured by PQ3.**

	N	Minimum	Maximum	Mean	Std. Deviation
Interfere daily function - 1	13	2	5	3.54	.877
Interfere daily function - 2	13	1.00	5.00	2.8462	1.14354
Interfere daily function - 3	13	1.00	5.00	2.2308	1.16575
Valid N (listwise)	12				

Table 4.38 shows descriptive Statistics – Group 3 as measured by PQ3.

**Table 4.39 Descriptive Statistics - Group 3 as measured by PQ4.**

	N	Minimum	Maximum	Mean	Std. Deviation
Noticibility to others - 1	13	1	5	2.54	1.266
Noticibility to others - 2	13	1.00	5.00	2.3077	1.18213
Noticibility to others - 3	13	1.00	5.00	2.0769	1.32045
Valid N (listwise)	12				





Table 4.39 shows descriptive Statistics - Group 3 as measured by PQ4.



## **4.11 SUMMARY OF REMEDIES PRESCRIBED**

The various remedies were prescribed at different potencies i.e. 30CH, 200CH, 1M or 10M. The tables below are a representation of the remedies and their corresponding potencies prescribed in the study, taking all three groups into account.





**Table 4.40 SUMMARY OF REMEDIES AND POTENCIES PRESCRIBED**





Remedies	Simillimun	Counselling	Placebo	Frequency
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	Group	Group	Group	of Prescriptions
1. Anacardium Orientale  <a href="http://images.google.co.za/">http://images.google.co.za/</a>			200/ M	1
2. Argentum Nitricum  <a href="http://images.google.co.za/">http://images.google.co.za/</a>	30/200/M (x2)			2
3. Arsenicum Album  <small>© DHU, Karlsruhe</small> <a href="http://images.google.co.za/">http://images.google.co.za/</a>		30/200/M		1
4. Arundo donax  <a href="http://images.google.co.za/">http://images.google.co.za/</a>			30	1
5. Aurum metallicum			30/200/M	1

 <p><a href="http://images.google.co.za/">http://images.google.co.za/</a></p>				
<p>6. Bryonia alba</p>  <p><a href="http://images.google.co.za/">http://images.google.co.za/</a></p>		30/200/M		1
<p>7. Calcareo Carbonica</p>  <p><a href="http://images.google.co.za/">http://images.google.co.za/</a></p>	30/200/M			1
<p>8. Carcinosinum</p>	200	30/200/M	200/M	3
<p>9. Causticum</p>	30/200/M			1
<p>10. Gelsemium sempevirens</p>	30/200/M (x2)		30/200/M (x2)	4

 <p><a href="http://images.google.co.za/">http://images.google.co.za/</a></p>				
<p>11. Ignatia amara</p>  <p><a href="http://images.google.co.za/">http://images.google.co.za/</a></p>	10M		200/M	2
<p>12. Kalium Muriaticum</p>  <p><a href="http://images.google.co.za/">http://images.google.co.za/</a></p>		30/200/M		1
<p>13. Lac caninum</p>  <p><a href="http://images.google.co.za/">http://images.google.co.za/</a></p>			30/200/M	1
<p>14. Lachesis muta</p>	30/200/M			1

 <p><a href="http://images.google.co.za/">http://images.google.co.za/</a></p>  <p><a href="http://images.google.co.za/">http://images.google.co.za/</a></p>				
<p>15. Lycopodium clavatum</p>  <p><a href="http://images.google.co.za/">http://images.google.co.za/</a></p>		200		1
<p>16. Medorrhinum</p>		30/200/M		1
<p>17. Mercurius Solubilis</p>  <p><a href="http://images.google.co.za/">http://images.google.co.za/</a></p>			30/200/M	1
<p>18. Natrum</p>	30/200/M (x4)	30/200/M	30/200/M (x3)	8

<p>Muriaticum</p>  <p><a href="http://images.google.co.za/">http://images.google.co.za/</a></p>  <p><a href="http://images.google.co.za/">http://images.google.co.za/</a></p>				
<p>19. Nux vomica</p>  <p><a href="http://images.google.co.za/">http://images.google.co.za/</a></p>	30/200/M	30/200/M (x2)		3
<p>20. Phosphorus</p>  <p><a href="http://images.google.co.za/">http://images.google.co.za/</a></p>		30/200/M	30/200/M	2
<p>21. Platinum metallicum</p>	M			1

 <p><a href="http://images.google.co.za/">http://images.google.co.za/</a></p>				
<p>22. Pulsatilla Nigricans</p>  <p><a href="http://images.google.co.za/">http://images.google.co.za/</a></p>	200	30/200/M (x2)	30/200/M (x2)	5
<p>23. Rhus Toxicodendron</p>  <p><a href="http://images.google.co.za/">http://images.google.co.za/</a></p>			30/200/M	1
<p>24. Sepia</p>			30/200/M	1

 <p><a href="http://images.google.co.za/">http://images.google.co.za/</a></p>				
<p>25. Silicea</p>  <p><a href="http://images.google.co.za/">http://images.google.co.za/</a></p>		30/200/M		1
<p>25. Staphysagria delphinium</p>  <p><a href="http://images.google.co.za/">http://images.google.co.za/</a></p>			30/200/M (x3)	3
<p>26. Thuja Occidentalis</p>  <p><a href="http://images.google.co.za/">http://images.google.co.za/</a></p>			30/200/M	1

Table 4.40 shows summary of the remedies prescribed, the potencies and the

frequency of prescription for each remedy.

Where: x = number of times the remedy was prescribed in that particular group.

30 = 30 Centesimal potency

200 = 200 Centesimal potency

M = 1 Millesimal potency

10 M = 10 Millesimal potency

30/200/M = means three powdered potencies (powder no.1 = 30CH, powder, no. 2 = 200CH and powder no. 3 = M).

**Table 4.41 shows remedies and potencies in the Simillimum group**

<b>PARTICIPANT</b>	<b>REMEDY AND POTENCY AT INITIAL CONSULTATION</b>	<b>REMEDY AND POTENCY AT SECOND CONSULTATION</b>
1	Nux vomica 30CH/200CH/M	Sac-lac (1-3)
2	Argentum nitricum 200CH (1-3)	Causticum 30CH/200CH/M
3	Gelsemium sempevirens 30CH/200/M	Gelsemium sempevirens 30CH (1-2) /200CH (3)
4	Lachesis muta 30CH/200CH/M	Sac-lac (1-3)
5	Natrum muriaticum 30CH/200CH/M	Natrum muriaticum 30CH (1-2)/ 200CH/(3)
6	Platinum metallicum M(1)/Sac-lac (2-3)	Sac-lac (1-3)
7	Natrum muriaticum 30CH/200CH/M	Sac-lac (1-3)
8	Natrum muriaticum 30CH/200CH/M	Sac-lac (1-3)
9	Argentum nitricum 30CH/200CH/M	Sac-lac (1-3)
10	Carcinosinum 200CH (1-3)	Sac-lac (1-3)
11	Pulsatilla Nigricans 200CH (1-3)	Ignatia amara 10M (1) Sac-lac (2-3)

Table 4.41 is a summary of the remedies and the potencies prescribed at each

consultation within the Similimum group.

Where: x = number of times the remedy was prescribed in that particular group.

30 = 30 Centesimal potency

200 = 200 Centesimal potency

M = 1 Millesimal potency

10 M = 10 Millesimal potency

Sac-lac = unmedicated/ inactive powder

30/200/M = means three powdered potencies (powder no.1 = 30CH, powder, no. 2 = 200CH and powder no. 3 = M)

**Table 4.42 shows remedies and potencies in the Psychological Counselling**

**Group.**

PARTICIPANT	REMEDY AND POTENCY AT INITIAL CONSULTATION	REMEDY AND POTENCY AT SECOND CONSULTATION
1	Bryonia alba 30CH/200CH/M	Carcinosinum 30CH/200CH/M
2	Arsenicum Album 30CH/200CH/M	Sac-lac (1-3)
3	Pulsatilla Nigricans 30CH/200CH/M	Pulsatilla Nigricans 200CH (1-3)
4	Natrum muriaticum 30CH/200CH/M	Sac-lac (1-3)
5	Phosphorus 30CH/200CH/M	Sac-lac (1-3)
6	Nux vomica 30CH/200CH/M	Sac-lac (1-3)
7	Kalium muriaticum 30CH/200CH/M	Sac lac (1-3)
8	Calcarea carbonica 30CH/200CH/M	Sac lac (1-3)
9	Silicea 30CH/200CH/M	Sac lac (1-3)
10	Medorrhinum 30CH/200/M	Lycopodium clavatum 200CH(1-2), Sac lac (1-3)

Table 4.42 is a summary of the remedies and the potencies prescribed at each consultation within the Psychological Counselling group.

Where: x = number of times the remedy was prescribed in that particular group.

30 = 30 Centesimal potency

200 = 200 Centesimal potency

M = 1 Millesimal potency

10 M = 10 Millesimal potency

Sac-lac = unmedicated/ inactive powder

30/200/M = means three powdered potencies (powder no.1 = 30CH, powder no. 2 = 200CH and powder no. 3 = M).

**Table 4.43 shows remedies and potencies in the Placebo Group.**

<b>PARTICIPANT</b>	<b>REMEDY AND POTENCY AT INITIAL CONSULTATION</b>	<b>REMEDY AND POTENCY AT SECOND CONSULTATION</b>
1	Gelsemium sempevirens 30CH/200/M	Lac-can 30CH/200CH/M
2	Natrum muriaticum 200CH (1-2)/M(3)	Ignatia amara 200CH (1-2)/M (3)
3	Staphysagria M(1-3)	Sac-lac (1-3)
4	Carcinosinum  200CH (1-2)/M (3)	Sac-lac (1-3)
5	Anacardium orientale  200CH (1-2)/M (3)	Mercurius solubilis  30CH/200CH/M
6	Thuja occidentalis  30CH/200CH/M	Aurum metallicum  30CH/200CH/M
7	Natrum muriaticum 30CH/200CH/M	Sac-lac (1-3)
8	Sepia 30CH/200CH/M	Rhus toxicodendron 30CH (1-3)
9	Pulsatilla nigricans  30CH/200CH/M	Pulsatilla nigricans  30CH/200CH/M
10	Staphysagria  30CH/200CH/M	Arundo donax  30CH (1-3)
11.	Staphysagria  30CH (1)/200CH (2-3)	Staphysagria  200CH (1-3)
12	Phosphorus 30CH/200CH/M	Sac-lac (1-3)

13	Gelsemium sempevirens 30CH/200CH/M	Natrum muriaticum 200CH (1-3)
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Table 4.43 is a summary of the remedies and the potencies prescribed at each consultation within the Placebo group.

Where: x = number of times the remedy was prescribed in that particular group.

30 = 30 Centesimal potency

200 = 200 Centesimal potency

M = 1 Millesimal potency

10 M = 10 Millesimal potency

Sac-lac = unmedicated/ inactive powder

30/200/M = means three powdered potencies (powder no.1 = 30CH, powder no. 2 = 200CH and powder no. 3 = M).

## CHAPTER FIVE

### 5.1 Discussion

The purpose of this double-blind placebo-controlled study was to evaluate the relative efficacy of homoeopathic simillimum treatment as compared to psychological counselling (CT and BT) in the management of GAD, by means of the Hamilton Anxiety Rating Scale (Appendix F), the Beck Anxiety Inventory (Appendix G), and the Patient Perception Questionnaire (Appendix H).

The results show that the demographic data although representing a small sample does generally support the epidemiology ratio of women to men of 2:1 (Kaplan and Sadock, 1996:214). The current study showed that 58.82% females were suffering with GAD as opposed to 41.18% males (1.7: 1.2). The incidence in the current study in terms of age is the late 20s which concurs with Kaplan and Sadock's observation that patients usually seek attention in their 20's. The results of this current study show that the average age was 29 years.

Intra-Group analysis of data obtained from the Hamilton Anxiety Rating Scale (Appendix F), the Beck Anxiety Inventory (Appendix G) and the Patient Perception Questionnaire (Appendix H) using the Wilcoxon signed rank test showed that each intervention resulted in an improvement in GAD symptoms. However, to determine which intervention was most effective in the treatment of GAD, inter-group analysis of data

obtained from the Hamilton Anxiety Rating Scale (Appendix F), the Beck Anxiety Inventory (Appendix G) and the Patient Perception Questionnaire (Appendix H) using the Kruskal Wallis test was done.

The results showed no significant statistical difference between the three groups (Simillimum, Psychological Counselling and Placebo). Therefore, according to this study, homoeopathic simillimum treatment was no more effective than the psychological counselling (CT and BT) or placebo in the management of GAD.

The results observed in this study concur with that of Bonne et al. (2003) who used similar measuring tools in order to compare homoeopathic simillimum with placebo i.e. both groups (simillimum and placebo) showed some improvement in the anxiety symptoms, however, neither intervention proved to be more superior than the other.

Some similarities exist between the current study and that done by Borkovec and Castello (1993, 611-619), where they assessed the effectiveness of three treatments for GAD, (non-directive therapy, applied relaxation therapy and cognitive-behavioural therapy), in that they also found that improvement was evident amongst all groups. However, they found that those in the applied relaxation and cognitive-behavioural treatment group showed superior benefits over placebo. This does not concur with the current study in which cognitive therapy and behavioural therapy did not prove to have a more beneficial effect than placebo in the treatment of GAD.

Research conducted by Louw (2003) showed that homoeopathic simillimum in conjunction with rational behaviour therapy proved statistically superior to placebo and rational behaviour therapy in patients with dysthymic and adjustment disorder regarding patients ability to deal with cognitive distortions during group therapy in terms of the Beck Depression Inventory and YUPI scales. A direct comparison of results is not possible due to the many methodological differences of the studies. These differences are as follows:

Table 5.1 Comparison of Differences.

<b>CURRENT STUDY</b>	<b>LOUW'S STUDY</b>
<p data-bbox="186 856 422 892">✚ <u>Duration:</u></p> <p data-bbox="186 924 747 1102">The duration of the current study was four weeks; two follow up consultations at two-week interval.</p>	<p data-bbox="771 856 1006 892">✚ <u>Duration:</u></p> <p data-bbox="771 924 1331 1102">The duration of this study was nine weeks; three follow up consultations at three-week interval.</p>
<p data-bbox="186 1220 568 1255">✚ <u>Treatment protocol:</u></p> <p data-bbox="186 1365 747 1837">In the current study there were three groups (Simillimum group = homoeopathic consultation+ active powders, Psychological Counselling group= homoeopathic consultation + inactive powders + psychological counseling, and Placebo =</p>	<p data-bbox="771 1220 1153 1255">✚ <u>Treatment protocol:</u></p> <p data-bbox="771 1365 1331 1837">In this study there were two groups (Treatment group = homoeopathic consultation + psychological counseling + active powders and Placebo group = homoeopathic consultation + psychological counseling + inactive powders).</p>

homoeopathic consultation+ inactive powders).	
<p>✚ <u>Measuring tools:</u></p> <p>In the current study there were three measuring scales ( the Hamilton Anxiety Rating Scale, the Beck Anxiety Inventory and the Patient Perception Questionnaire)</p>	<p>✚ <u>Measuring tools:</u></p> <p>In this study there were only two measuring scales (the Beck Depression Inventory and the YUPI scale.</p>
<p>✚ <u>Number of powders:</u></p> <p>There were three powders prescribed in the first and second consultation</p>	<p>✚ <u>Number of powders:</u></p> <p>There were five powders prescribed in the first consultation</p>
<p>✚ <u>Counselling:</u></p> <p>The psychological counseling was individually based.</p>	<p>✚ <u>Counselling:</u></p> <p>The psychological counseling was a group therapy.</p>
<p>✚ <u>Statistical analysis:</u></p> <p>Quantitative analysis.</p>	<p>✚ <u>Statistical analysis:</u></p> <p>Qualitative and quantitative.</p>

Table 5.1 shows the differences that exist between the current study and that done by Louw, N. 2003.

Power, Simpson, Swanson and Wallace (1990: 267-292) conducted a study comparing cognitive-behavioural therapy, diazepam and placebo, alone and in combination, in the treatment of GAD. The results demonstrated that the greatest amount of positive changes was produced by cognitive-behavioural treatment and cognitive-behavioural treatment combined with medication. This however, does not concur with the results obtained from the current study in which cognitive therapy and behavioural therapy did not prove to have more beneficial effects on anxiety symptoms than the homoeopathic medication or placebo.

An important component of this discussion is the possible effect of a placebo. Placebo is a substance with no active biological properties. In a controlled clinical trial, it is used as an inactive agent that plays the role of a standard of comparison for the substance or method to be tested and is indistinguishable from it (Swayne, 2000: 162). However, in the current study, one can question the 'inactive' nature of the placebo.

For the purpose of this trial, placebo was used as a control, to determine the effectiveness of the homoeopathic simillimum as compared to psychological counselling. The fact that the participants in the placebo group were listened to with sympathy, and received something i.e. an oral dose of an 'inactive' substance indistinguishable from an active homoeopathic simillimum could have been enough to help them improve their symptoms.

However, this then raises an important question: will every placebo group improve to a

certain degree and if so, is this an effective means by which to compare a new intervention? How much of a placebo improvement is allowed to approve or disapprove the effectiveness of an intervention.

According to Benson and Friedman (1996: 194-195), the placebo is the aspect of treatment not attributable to specific pharmacologic or physiologic properties. They have proposed that the determinants of the placebo effect are a positive belief and expectation on the part of the patient, a positive belief and a positive belief of expectation on the part of the physician, and a good relationship existing between both the patient and physician. It is possible that all three determinants were in place during this study. All three groups in this study received an oral dose of a 'medicine' i.e. powders, thus the positive improvement within all the groups could be attributable to this placebo effect.

Another placebo effect to consider is that of the homoeopathic consultation itself, which provided an opportunity to talk about anxieties, and express underlying emotions, in a safe and supportive environment. This in itself could have contributed to improvement of symptoms.

From experience and the literature, it seems that healing from deep trauma comes from facing it openly and retelling the event repeatedly, allowing natural healing mechanisms to operate that are capable of dealing with emotional damage caused by trauma. Such healing mechanisms include crying, laughing and angry raging (Bogorad, 2003). All of

these were observed in this study during the consultations.

As was evident in the participants' narratives, most of them had anxiety being caused by different kinds of traumas and grief. Aetiologies included sexual molestation; physical, emotional and verbal abuse; exposure to violent crimes; neglect; and family disputes. There were many cases involving domineering parents and high expectations from loved ones with a resulting fear of failure and the consequences of failure.

Over a long enough period, anxieties associated with the above aetiologies can produce physical symptoms such as heart palpitations, increased blood pressure, muscle tension, insomnia, and gastric complaints, to mention a few. The researcher did encounter such symptoms amongst the participants. This concurs with the related literature on suppression of mental-emotional symptoms (Roberts, 1993: 38) and psychoneuroimmunological theory (Pitts and Phillips, 1998: 61-65).

The researcher believes that our cultural 'norms' often place restrictions on healing mechanisms, an example being that 'big boys don't cry'. It was very challenging to overcome these obstacles, but the homoeopathic consultation did seem to provide an ingredient, which allowed the various healing mechanisms to work, because some 'big boys' did cry!

One may ask that since all three groups experienced the 'effect' of the homoeopathic consultation, and were administered powders (active or 'inactive'), why did the

Psychological Counselling group, which received an additional psychological intervention, not prove superior to both the Simillimum group and the Placebo group? This group had double the consultations (homoeopathic and counselling) and 'medication', whereas the Simillimum and Placebo groups had only one consultation and 'medication'. This observation tends to reinforce the point made earlier that perhaps the primary force for the placebo effect was in fact the administration of medication, whether active and 'inactive'.

The researcher is of the opinion that a possible further explanation for the lack of 'extra' improvement in the counselling group could have been the short duration of such counselling. Short duration would have made it difficult for participants to fully understand and apply the skills or techniques obtained during the psychological counselling sessions. Research has shown that it is vital that patients apply new perceptions of how the brain functions and the related skills in order to harness the newly learned information (Maultsby, 1984). The aim of the counselling sessions in this study was to change existing perceptions of the anxious patients and put new ones into practice. In this process, intellectual insight development was a vital step in the emotional re-education process.

According to Maultsby (1984), when we receive new information and our perceptions start changing through the process of emotional re-education, we start the process of challenging our old beliefs and motives. This is only half the process. In order to replace the old belief with a new one, the new perception upon which that new belief is based must be practiced mentally. The patient must visualize and practice feeling and behaving the way they want to in a familiar situation. When this does not happen then

the therapy cannot be beneficial. This is an extremely uncomfortable process as patients confront their hidden motives and emotional experiences in order to replace them with ones that are more desirable. People have a tendency to solve this discomfort by resorting back to old beliefs and behaviours because new learning is difficult and requires effort (Maultsby, 1998). The tendency to resort back to old ways of thinking does not come as a surprise. It is not only part of human nature but also part of a universal law of nature, the law of entropy<sup>1</sup>. Human nature is one that seeks pleasure and gratification, so the discomfort and the pain involved in solving problems is avoided as far as possible. Often a person will go to great lengths to avoid such pain, even as far as constructing fantasies in which to live, sometimes to the total exclusion of reality (Peck, 1978). However, as Peck says, “the more clearly we see the reality of the world, the better equipped we are to deal with the world” (Peck, 1978: 45).

If this process i.e. lack of implementation of skills or techniques obtained during psychological counselling sessions did occur in the current study, the effect of the counselling would have not been optimal or may have been compromised.

Regarding the homeopathic prescriptions, it is interesting to note the remedies most commonly prescribed, and see why this may be. The full list of remedies prescribed and their frequency of prescription is to be found in Table 4.40. Each prescription was based on a full, detailed homoeopathic case history (Appendix C) and physical examination (Appendix D). Analysis of the resulting case history narrative resulted in the researcher

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<sup>1</sup> The law of entropy states that a higher level of energy and structural organization always tend to move to a lower level of energy and structural organization. It is this inherent tendency in nature and particularly human nature that drives humans back to their comfort zones and old ways of thinking, since it requires less effort and energy to stay in a fixed pattern than to unlearn it and replace it with a new and foreign

arriving at the simillimum. This became the basis upon which medicine was selected for each patient. The researcher used the homoeopathic materia medica and homoeopathic repertory to confirm the selection of each appropriate simillimum remedy. The main remedies were as follows:

**Natrum muriaticum:**

Source: common rock salt

Keynote: Suppression of emotional pain

It is the predominant type in the modern times, a reflection of the suppressed emotional pain that is engendered by the average upbringing in today's society. Furthermore the most Natrums are so good at disguising their inner pain and vulnerability.

The emotional pain that is at the centre of Natrum's pathology originates early in childhood, when the unconditional love that the child needs is not received. Inability to let go of emotions, to let go of the loved ones, fear of expressing emotions, of losing loved ones, of rejection (Bailey, 1995: 175).

**Pulsatilla nigricans:**

Source: Wind flower

Keynote: The feminine principle

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pattern (Peck, 1978).

Mild, gentle, yielding disposition. Easily offended, weeps easily, easily discouraged, fear of being alone. Changeable symptoms and moods. Moody and vulnerable, whining, clinging, craves company and attention (Bloch, 2003: 93).

**Gelsemium sempevirens:**

Source: Yellow jasmine

Keynote: Weakness of the whole body

Centres its action upon the nervous system, causing various degree of both mentally and physical weakness. Bad effects from fright, fear and exciting news. Nervous dread of appearing in public. Utter lack of courage. Anticipation anxiety (Vermeulen, 1994: 448-449).

**Nux vomica:**

Source: Poisonous nut

Keynote: The conqueror

The most universal fundamental aspect is a love of power, and the ability to acquire power and exercise it with confidence. Success is not enough for, but it is winning that gives meaning to life. Very irritable, angry and impatient and violent (Bailey, 1995: 227).

**Staphysagria delphinium**

Source: Louse wort

Keynote: Suppressed anger

The anger is often so well suppressed that it is not only unexpressed; it is not even felt.

This can give a mellowness or sweetness that belies the time-bomb of anger ticking away beneath the surface of consciousness. The source of suppression is usually found in the early childhood. The parents were often restrictive and authoritarian, or the parents put the child down verbally, telling him or her that he or she was 'good for nothing' (Bailey, 1995: 321).

### **Carsinosinum**

Source: Nosode from carcinoma

Keynote: Perfectionism

Very sensitive, fastidious, perfectionistic. Sympathetic. Love of animals. Strong sense of duty. Too much responsibility at a young age. History of domineering parents (Vermeulen, 1994: 266).

## **5.2 Limitations to this trial**

Viewing the results of this trial retrospectively, some of the research areas could have been refined to allow more positive outcome.

Most participants had been suffering from GAD for many years and months, therefore their condition had been longstanding and of chronic nature thus requiring treatment over a longer period, the duration of this study was too short and future trials should be carried out over a longer period to allow medication to act fully. A period of more than 6 months at the least.

A larger sample size for future research is suggested, in order to obtain greater statistical accuracy.

High expectancy levels of patients proved challenging, some participants expected a 'miracle pill' that could take away their anxieties and worries within a short space of time, whilst some of the participants were reluctant to discuss their deeper emotional issues, which made simillimum prescription challenging, as thorough case-taking is integral in arriving at the simillimum.

With this kind of research, when something as subjective as GAD is investigated, how do we clearly define all or the important variables and by which or who's standard do we evaluate them? If the condition or dis-ease is primarily a subjective experience, then shouldn't the criteria for improvement also be.

Potencies of medicines were not standardized as it varied for each participant; this however made no impact on differentiation between the active and placebo medicaments. However it is of the researcher's opinion that LM potencies could have had more beneficial results had it been administered in this trial instead of centesimal potencies. This perception is due to the fact that GAD is a long-standing (chronic) condition as it has been discussed in the related literature (Refer Chapter 2), thus the rationale for the LM potency as these potencies are stated to be quicker, deeper acting, cause less aggravations if any. There is no leap or jump in this method (in potencies). In long-time suppression, this potency works very effectively. The LM potency is excellent in palliating incurable diseases without the danger of aggravation. Lastly, they could be taken over a long period of time (de Schepper, 2001: 100). However, the administration of the LM potency could not be possible because of budget constraints.

Although the researcher had an understanding of the simillimum approach and received clinical supervision, she was still relatively inexperienced in homoeopathic practice; this may have contributed negatively to the results. Further studies conducted involving homoeopathic simillimum where practically possible should incorporate a quality control mechanism whereby such interpretation of cases are simultaneously verified by more than one independent clinicians.

The current standard practice is that a homoeopathic student takes the full homoeopathic case history and does the full physical examination and then discusses the case with the clinician on duty.

## CHAPTER SIX

### Conclusion and Recommendations

#### 6.1 Conclusion

The results obtained from this study lead to the conclusion that homoeopathic simillimum treatment is not more effective than psychological counselling (CT and BT) or placebo in the management of GAD.

An inherent problem in clinical studies involving homoeopathic simillimum is the paradigm in which the results are analyzed. Today everything must be measured. This has resulted in quantification of everything with the consequence that those phenomena and experiences which are qualitative are denigrated and even regarded as having no reality. All our inner life, our souls, emotions are qualitative. To exclude these is to exclude our very human reality and we are today in great danger of forgetting that we are the measurers and not only measurable objects (Twentyman, 1989, 35).

The consultation that lasted for an hour to an hour and one-and-a-half hours allowed patients to express negative emotions and seemed to help them feel better at the end of each consultation. This process could have been therapeutic in itself to help patients, thus contributing to the improvement demonstrated in all three groups.

Furthermore, the placebo responses are augmented by the very nature of this study, the

reason being that the placebo targets the patient's superficial perception and expectation. When a patient seeks professional help, he or she expects to get better and this expectation is enhanced when he or she receives medication (Hanekom, 2002: 4-9). In this study, therefore, one can say that the placebo effect inherently targeted one of the variables of interest in this study, as it works at a perceptual level.

### **6.1.1 Benefits of the study**

- 1 Participants gained information about homoeopathy. Most of them had little understanding of what homoeopathy is and began to appreciate the profession as a natural complementary method, in its holistic approach.
- 2 Participants gained more knowledge about their bodies and their health, especially regarding the connection between mental/psychological symptoms and physical symptoms.
- 3 Participants were educated on the condition itself, GAD.

## **6.2 Recommendations**

The execution and the analysis of this research study lead the researcher to make the following recommendations to any potential researcher who desires to embark him/herself on this topic:-

- 1 The sample size used in further investigations could be larger in order to obtain greater statistical accuracy.

- 2 The duration of this trial was four weeks. In further studies/ investigations a longer trial period might be used.
- 3 In further studies / investigations, different potency could be used, for example- liquid potency (LM or 30-plussed potency).
- 4 The frequency of administration of the remedy could be taken differently than in this study maybe once a week.
- 5 Investigate the management of GAD combining both simillimum and counselling.
- 6 Investigate the management of GAD using a herbal tincture/ phytotherapy.
- 7 Research comparing homoeopath remedies and the management of GAD with other complementary modalities such as chiropractic, reiki, crystal therapy, acupuncture and phytotherapy.
- 8 GAD is a multifaceted problem therefore it is recommended that homoeopathic treatment be evaluated together with lifestyle adjustments such as diet and exercise.

- 9 Further studies should investigate the long-term benefits of treatment to participants and their general integration as coping individuals back into society. A prospective follow-up study could prove useful to assess the long-term affects of homoeopathic and psychological counselling therapy, since anxiety tends to follow a relapsing and remitting course.
- 10 Compare samples from different socio-economic or from different cultural or different genders to determine if these variables have any influence on outcome.
- 11 A clinical trial method that is worth considering is the cross over design that is designed as a repeated measure design to control order effects when comparing two treatments. In this design, half the sample receives treatment A first followed by treatment B, and the other half receives treatment B first followed by treatment A, This method is useful because it requires fewer participants because participants act as their own controls. This design assures that any effect due to the order of treatment is eliminated from the observed treatment (Portney and Watkins, 1993: 681).
12. Further studies conducted by students involving homoeopathic simillimum where practically possible should incorporate a quality control mechanism whereby one clinician only is utilized or group of independent clinicians.
13. A study aiming to determine the effect of the homoeopathic consultation.



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**APPENDIX - A**



**SUBJECT INFORMATION LETTER**

TITLE OF RESEARCH PROJECT:

The relative efficacy of Homoeopathic Simillimum treatment as compared to psychological counseling (Cognitive Therapy and Behavioral Therapy) in the management of Generalized Anxiety Disorder (GAD).

**NAME OF SUPERVISOR:** *Dr. David Naude, M.Tech.Hom. (TN)*

NAME OF CO-SUPERVISORS: Dr. Madhu Maharaj, M.Tech. Hom. (T.N.)

Ms. Karen Roodt, B(ED) (Psych);  
MED (Counseling and Guidance)  
Registered Psychologist (HPCSA)

NAME OF RESEARCH STUDENT: Jabulile Ngobese

Date:.....

Dear Participant

Thank you for your time and interest in reading this letter. With your assistance the effectiveness of Homoeopathic treatment in Generalized Anxiety Disorder can be investigated.

I am a homoeopathy student at the Durban Institute of Technology. In order to qualify as a Homoeopath, a mini-dissertation has to be completed. This study will assess the effectiveness of homoeopathic treatment in managing Generalized Anxiety Disorder .In order to do this, I appeal to you for your assistance by becoming actively involved and informing me about your symptoms before and during the study as well as their effect on your daily lives.

This clinical trial will be conducted at the Homoeopathic Day Clinic under the supervision of a qualified and registered homoeopath. Each participant must comply with the selection criteria in order to participate in this study. **The study will include those that fulfill the following criteria:**

1. Patients may be male or female.
2. Patients have to be between the ages of 18 and 60 years.
3. You patients have to fit the diagnostic criteria for 300.02 Generalized Anxiety Disorder according to DSM IV:
  - \* Excessive anxiety and worry (apprehensive expectation), occurring more days than not for at least 6 months about a number of events or activities, (such as work or school performance).
  - \* The person finds it difficult to control the worry.
  - \* The anxiety and worry are associated with three (or more) of the following six symptoms (with at least some symptoms present for more days than not for the past 6 months).
    1. Restlessness or feeling keyed up or on edge
    2. Being easily fatigued
    3. Difficulty concentrating or mind going blank
    4. Irritability
    5. Muscle tension
    6. Sleep disturbance (difficulty falling or staying asleep, or restlessness and unsatisfying sleep)
  - \* The anxiety and worry is not about having panic attack or being embarrassed in public, being contaminated, being away from home or close relatives, gaining weight, having multiple physical complaints, or having serious illness and the anxiety and worry do not occur exclusively during Post Traumatic Stress Disorder.
  - \* The anxiety and worry or physical symptoms cause clinically signified distress or impairment in social, occupational, or other important areas of functioning.
  - \* The disturbance is not due to the direct physiological effects of a substance (e.g. a drug of abuse, a medication) or a general medical condition (e.g., hyperthyroidism) and does not occur exclusively during a Mood Disorder, a Psychotic Disorder, or a Pervasive Developmental Disorder.

**Those participants with the following conditions will be excluded in this study:**

1. Pregnant women, lactating women, undergoing any other form of treatment or medication for Generalized Anxiety Disorder.
2. Participants must not be on any other treatment (except the chronic medication used for unrelated conditions; e.g. hypertension, diabetes, hypercholesterolaemia ) and/or intervention for GAD whilst in the study.
3. Patients suffering from any other psychological disorder i.e. Depression, Mental Disorder.
4. Patients suffering from hypoglycemic episodes, hyperthyroidism, cardiac arrhythmias, caffeineism, pheochromocytoma, and seizure disorders.

If you fulfill the selection criteria, and are willing to participate, you will be accepted into the study group. This study will last for 6 weeks and the researcher will need to see you for 3 consultations during this time.

At the consultations you will be required to fill in four questionnaires available in Zulu and English. All information will be kept confidential. Once the dissertation is published, the case files will be destroyed. The names of the participants will not appear in the dissertation.

This study is a double-blind placebo controlled study. This means that you have 33% of receiving either treatment or placebo or placebo and psychological therapy. Placebo medication looks and tastes the same as the active medicine, but is neutral. Participants who receive placebo will receive free treatment at the end of the study. Treatment will be dispensed by the homoeopathic clinic dispenser.

“Double-blind” refers to the fact that the neither researcher nor the patient will know who is receiving what and patients will be advised not to disclose the information as to who is seeing a psychologist. This will only be known at the end of the data collection phase of the study, when the code is broken in order to analyze the data statistically.

Your participation in this study is on a voluntary basis and the consultation and treatment costs will be covered by the Durban Institute of Technology.

If you have any questions about the study or you feel that your condition is getting worse, please contact my supervisor or me so that you may be referred to a psychologist or a psychiatrist . You will not be denied any allopathic medication if you feel that you need to take it and you are free to withdraw from this study at any time without having to give a reason for withdrawing, and without affecting your future health care.

Dr. David Naude: M.Tech.Hom. (T.N.) (031) 204 2041  
Jabulile Ngobese: (Researcher) (083 526 3746)

Thank you for the courtesy of your assistance.

.....  
JABULILE NGOBESE  
DEPT OF HOMOEOPATHY (DIT)

.....  
Dr. David Naude: M.Tech. Hom. (T.N.)  
Clinic Director and Supervisor  
Dept. of Homoeopathy (DIT)

ISELEKO - A



**INDIKIMBA YENCWADI YENCAZELO**

**ISIHLOKO SOMKLAMO WOCWANINGO:**

**Umpumela wekhambi leHomoeopathy uma uliqhathanisa nokuhlengwa ngodokotela wezemcabango nezomphefumulo uma kuhlengwa isimo sokukhathazeka kakhulu empilweni okuvamileyo nokubandezeka okuhambisana novalo.**

**IGAMA LOMHLOLI:**

Dr. David Naude  
M.Tech.Hom.(T.N.)

**IGAMA LABABAMBISENE NOMHLOLI:**

Dr. Madhu Maharaj,  
M.Tech.Hom. (T.N.)

Ms. Karen Roodt, B(ED) (Psych);  
MED (Counselling and  
Guidance)  
Registered Psychologist  
(HPCSA)

**IGAMA LOMFUNDI OWENZA UCWANINGO:** Jabulile Ngobese

**USUKU:** .....

**NGIYAKUBINGELELA MHLANGANYELI**

Siyabonga ngesikhatsi sakho nesineke sakho, nokukhathalela ukufunda lenchwadi. Ngosizo nangokuxhasa kwakho lenkinga yokuqala ngoku khathazeka kakhulu kuzoba empilweni evamileyo kanye nokubandezeka okuhambisana novalo nempumelelo okuphenyeni nasekuhloleni lenkinga.

Mina ngingumfundi owenza i homeoeopathy esikhungweni sezemfundo ephakeme i DIT. Ukuze ngiphumelele ekugogodeni ezifundweni zami zobuDocotela kwiHomoeopathy, lolucwaningo olufushane kumele luphuthuliwe.

Lolucwaningo luhlaziya futhi luhlole indlela esebenza ngayo imithi yehoeopathy ekulapheni lenkinga yokubandezeka, nokukhathazeka kakhulu empilweni okuhambisana novalo.

Ukuze ke lokhu kwenzekwe, ngicela ukundlulisa isicelo sokubambisana nawe ngosizo lwakho ngokuba uzibandakanye kuloluphando nase kungisizeni ngezimpawu onazo mayelana nalokh kugula kokukhathazaka ngaphambi kokulashwa, nangesikhathi sokulashwa nangendlela ezithinta ngayo impilo yakho.

Lolucwaningo luzokwenzeka ekliniki lase homoeopathy e DIT ngaphansi komholi obhalise ngokusemthethweni nosezogodile kulezizifundo ze homoeopathy.

Umhlanganyeli ngamunye kumele ahlangebuzane nemigomo yalolucwaningo ukuze akwazi ukuba ibambe iqhaza lokuba kulashwe.

Lolucwaningo luzohlanganisa labo abahlangabezayo lemigomo elandelayo

1. Abahlanganyeli kungaba owesilisa noma owesifazane
  2. Abahlanganyeli kumele babe neminyaka ephakathi kuka 18 no 60.
  3. Abahlanganyeli kumele bahlangabezane nemigomo yaleninga ngokwe DSM IV 300. 02
    - Ukukhathazeka okeqile kanye nokubandezeka okuhambisana novalo(ngezinto ezingakenzeki nezilindelekile, lokhu kwenzekwe izinsuku eziningi okungaba izinyanga eziyisithupha noma ngaphezulu futhi kuphazamise umsebenzi wakho wesikole noma emsebenzini indlela osebenza ngayo.
    - Ukuthola kunzima ukuzithiba noma ukukugoba noma ukukugwema lokhu.
    - Ukukhathazeka nokubandezeka kuyaye kuhambisane nalezi aimpawu ezintathu ezilandeyayo ( ezinye izimpawu zibakhona kakhuku kunezinye futhi sezibe nesikhathi esilinganiselwa ezinganyeni eziyisithupha noma ngaphezulu.
1. Ukuyaluyaluza, nokushobashoba noma ukuba nosikisiki.
  2. Ukushesha ukukhandleka ekuhlonzeni noma ukukhathala kalula.
  3. Ubunzima ekuhlonzeni noma ukuqoqela ndawomye umqondo nokuba umqondo ungakwazi ukujula uhlaziye kahle izinto.
  4. Ukuba nehliziyo encane esheshayo ukuhluthuka.
  5. Ukushaqeka nobuhlungu kweziqubu zomzimba.
  6. Ubuthongo nokulala okuphazamisekayo (ubunzima ukuthola mokuqwasha noma nokuphenduphenduka ebusuku noma ubuthongo).

- Ukukhathazeka nokubandezeka okuhambisana novala akungenxa yokwethuka noma ukuba namahloni nokusaba ukuphoxeka emphakathimi, noma ukungabi sekhaya lakho noma naseduze kwezihlobo zakho ukunyuka kwesisindo somziba wakho noma ukukhononda ngezifo senyama ezihlukehlukene, noma ukungaphatheki kahle emzimbeni ukugula nesifo esithite.
- Futhi lenkinga yokubandezeka nokukhathazeka ayibangelwa ukhlukumezeka ngenxa yento noma yesimo esedlulile sakudala awabhekana naso sakhathaza umphefumulo
- Ukubandazeka nokukhathazeka noma izimphawu zomzimba zibangela ukugula okusobala futhi kuyaxina kuphazamise inhlalakahle yakho emphakatsini, emsebenzini nakwezinye izindawo ophila kuzo.
- Lenkinga yokubandezeka ayibangelwa izithako oziphuzayo (njengezidakamizwa noma ukhlukumezeka imithi yokugula) noma ikhambi lokulapha ukusebenza ngokweqile kwendlala yegilo, futhi ayibangelwa inkinga yokhuthu noma ukuqumbelana, nesifo sengqondo kanye nomoya, nokuphatheka kabi enhliziyweni noma ngenxa yendlela yenkuliso ebangela ukuba ngumhlambi kazalusile.

**Labo bahlanganyeli abanalezi zimo ezilandelayo angeke bakwazi ukubandakanywa kulolucwaningo:**

1. Abesifazane abazithweleyo, abancelisayo, nalabo abaphuza imithi yalenkinga yokukhathazeka kakhulu nokubandezeka okuhambisana novalo.
2. Abahlanganyeli akumele babe kweminye imithi ngaphandle kwalabo abadla imithi nsukuzonke ngenxa yezifo ezingapheliyo ezingahlangene nalenkinga ecwaningwayo (njenge: hayihayi, isifo sikashukela, isifo samafutha maningi egazini), noma ukwelashelwa yona lenkinga ecwaningwayo ngenye indlela.
3. Abantu abanenkinga yengqondo noma eyaluphi uhlobo, isifo sokukhathazeka okujulile komphefumulo.
4. Abagula ngokuba babenezigameko zikashukela, igilo, inhliziyo, isithuthwane, isifo sendlala yezinso.

Uma ngabe uyahlangabezana nalemigomo ebekiweyo, futhi ube nesifiso sokuzibandakanya, uyobe-ke usumukelwa kulolucwaningo oluyoqhubq amasonto angu-6, futhi umcwaningi kuyodingeka ukuba akubone njalo emva kwama sonto amathathu.

Ngesikhathi sokubonwa uyobe sewucelwa ukuba ukhethe ukugcwalisa uhla lwemibuzo ngesiNgesi noma ngesiZulu. Yonke imininingwane yakho oyishoyo

iyogcinwa njengemfihlo, angeke idalulwe. Uma seluphothuliwe ucwaningo leyomininingwane iyobe isiyashatshaliswa. Amagama alabo abazibandakanyile kulolucwaningo angeke nawo adalulwe kucwaningo lwemibhalo.

Kulolu cwaningo akekho oyokwazi ukuthi ubani uthole hloboluni lomuthi kuze kuphele ucwaningo. Lokhu kusho ukuthi usethubeni elinganga maphesenti angu 33 okuthola ikhambi elinesithako sokwelapha, bese amanye amaphesenti angu 33 okuthola okunjegekhambi lokwelapha kodwa elingenaso isithako sokwelapha, Lamakhambi omabili abukeka ngokufana futhi anambitheka ngokufana.

Nama phesenti angu 33 okulashwa ngudokotela osebenza ngemicabango yomuntu nangemizwa yakhe. Labo bahlanganyeli abebethole ikhambi elingenaso isithako liyobe selithola ikhambi elibafaneleyo elinesithako sokwelapha mahhala emva kokuphothulwa kocwaningo. Imithi iyonikezwa umkhiphi mithi ekilini le Homoeopathy e DIT.

Umcwangingi akayikwazi ukuthi umuphi othole imithi enesithako nongayitholanga ngesizathu sokuthi kumele angabinakho ukwenzelela abese evuna uhlangothi lwakhe ngokuba azivumele. Lolulwazi uyoze aluthole uma sekuphothuliwe ucwaningo, ukuze akwazi ukuhlaziya kahle bese eloba ngokupheleleyo ngaleyo miphumela ayithole kulolu cwaningo.

Ukuzibandakanya kwakho kulolucwaningo kungukuzinikela kwakho ngentando, awuphoqiwe, konke ukwelashwa kwakho, nokubonwa kwakho kuyokhokhelwa ilesisikhungo sase DIT. Wena awukhokhi lutho.

Uma ngabe unemibuzo mayelana nalolucwaningo noma uzizwa sengathi inkinga yakho iqhubekela phambili, uyacelwa ukuba uxhumane noma uthintane nomhloli walolucwaningo noma nami uqobo, ukuze uzodluliselwa phambili kulabo abangakusiza, kungaba oDokotela abasebenza ngemicabango yomuntu nangengqondo yakhe noma abezifo zengqondo.

Angeke unqatshelwe ilungelo lakho lokuyakoDokotela bakho obajwayele nokuthatha imithi yakho oyejwayele uma uzwa ukuthi udinga ukuyithatha.

Wamukelekile ukuthi ungazihoxisa kulolucwaningo nanoma ingasiphi isikhathi ngaphandle kokuba unikeze isizathu, futhi lokho angeke kuphazamise indlela yakho yokwelashwa ngengomuso.

Dokotela: David Naude: M.Tech.Hom. (T.N.) (031) 204 2041  
Umcwangingi: Jabulile Ngobese (083 526 3746)

...

.....  
Jabulile Ngobese  
DEPT. OF HOMOEOPATHY (DIT)

.....  
Dokotela D. Naude: M.Tech. Hom. (T.N.)  
UMQONDISI NOMHLOLI  
DEPT. OF HOMOEOPATHY (DIT)

APPENDIX - B



**INFORMED CONSENT FORM**

TITLE OF RESEARCH PROJECT: *The effectiveness of homoeopathic simillimum in the management of Generalized Anxiety Disorder (GAD).*

**NAME OF SUPERVISOR:** *Dr. David Naude M.Tech.Hom.(T.N.)*

NAME OF CO-SUPERVISORS: Dr. Madhu Maharaj M.Tech.Hom.(T.N.)

Ms. Karen Roodt, B(ED) (Psych);  
MED (Counseling and Guidance);  
Registered Psychologist (HPCSA)

NAME OF RESEARCH STUDENT: Jabulile Ngobese

Date of first appointment:.....

PLEASE **CIRCLE** THE APPROPRIATE ANSWER

1. Have you read the subject information letter? YES/NO
2. Have you had an opportunity to ask questions regarding this study? YES/NO
3. Have you received satisfactory answers to your questions? YES/NO
4. Have you had an opportunity to discuss this study? YES/NO
5. Have you received enough information about this study? YES/NO
6. Who have you spoken to? .....
7. Do you understand the implications of your involvement in this study?  
YES/NO

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

YES/NO

- a). at any time
- b) without having to give a reason for withdrawing, and without affecting your future health care

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

YES/NO

If you answered NO to any of the above, please obtain the information before signing.

**PATIENT NAME (in block letters):**-----

SIGNATURE:-----

WITNESS NAME (in block letters):-----

SIGNATURE:-----

RESEARCH STUDENT NAME (in block letters):-----

SIGNATURE-----

**ISELEKO - B**



**NGENCAZELO YEMITHETHO**

**ISIHLOKO SOMKLAMO WOCWANINGO:**

**Umpfumela wekhambi le Homoeopathy uma uliqhathanisa nokuhlangwa ngodokotela wezemicabango nezomphefumulo uma kuhlangwa isimo sokukhathazeka kakhulu empilweni okuvamileyo nokubandezeka okuhambisana novalo.**

**Igama lomhloli:** Dr. David Naude, M.Tech.Hom. (T.N.)

**Igama lababambisene nomhloli:** Dr. Madhu Maharaj, M.Tech.Hom.(T.N.)

Ms. Karen Roodt, B(ED) (Psych);  
MED (Counselling and Guidance);  
Registered Psychologist (HPCSA)

**Igama lomfundi owenza ucwaningo:** Jabulile Ngobese

Usuku lokuqala lokubonwa.....

Uyacelwa ukuba / zongolozele leyo mpendulo oyikhethayo

1. Ingaba uyifundile indinkimba yencwadi yencazelo? ..... YEBO / CHA
2. Ingaba usutholile isikhathi / ithuba lokubuza imibuzo ..... YEBO / CHA  
kuleyo imibuzo yakho?
3. Ingaba uthole izimpendulo ezikugculisayo ..... YEBO / CHA  
kuleyo mibuzo yakho?

4. Ingaba ulitholile yini ithiba lokubonisana ..... YEBO / CHA  
nokuxoxisana ngalolucwaningo?

5. Ingaba unayo imininingwane eyanele ..... YEBO / CHA  
mayelana nalolucwaningo?

6. Ingaba ukhulume / ubonisane nobani? .....

7. Ingabe uyayazi yini imigomo yalolucwaningo ..... YEBO / CHA  
ozozibandakanye kulo?

8. Ingaba uyakuqonda yini ukuthi wamukelekile ukuba ..... YEBO / CHA  
uzihoxise noma inini kulolucwaningo?

(a) noma ingasiphi isikhathi

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

9. Ingaba uyavuma ukuzibandakanya, nokuthatha iqhaza ..... YEBO / CHA  
kulolucwaningo .

Uma ngabe ukhona umbuzo ophendule ngoCHA kuwo, zama ukuthola  
Ulwazi ngaphambi kokuba usayine isivumelwano.

Igama lomhlanganyeli / isiguli ( ngosonhlamvukazi, nokuhlukanisa)

.....

ISAYINI YESIVUMELWANO .....

IGAMA LOFAZI  
(NGOSONHLAMVUKAZI, NOKUHLAKANISA).....

ISAYINI YESIVUMELWANO .....

IGAMA LOMFUNDI OWENZA UCWANINGO  
(NGOSONHLAMVUKAZI, NOKUHLAKANISA).....

ISAYINI YESIVUMELWANO .....

**APPENDIX - C**

**CASE HISTORY QUESTIONNAIRE**

**DATE:**-----

SURNAME:-----PATIENT NO.:-----

FIRST NAMES:-----

AGE-----GENDER:-----

OCCUPATION-----

MARITAL STATUS:-----

CHILDREN:-----

ADDRESS:-----

-----CODE-----

TELEPHONE:-----

**MAIN COMPLAINT: WHAT SEEMS TO BE THE PROBLEM?**

**HISTORY OF THE MAIN COMPLAINT:**

- When did the problem start?
- How did it start?
- What are the symptoms of your problem?
- What was happening when the problem started?
- Is there anything that makes your problem better or worse?
- How has your problem affected you and your life?
- How do you feel about your problem?
- Do you have any fears?
- What are your concerns or worries about?
- What are your likes and dislikes?
- What makes you happy?
- What makes you angry or irritable?
- What are your concerns?

## **OTHER HISTORY:**

### **PAST MEDICAL HISTORY:**

Medical evaluation will include a complete medical history and a physical examination within the past 12 months, with special evaluation of conditions that may mimic anxiety disorders. These include hypoglycemic episodes, hyperthyroidism, cardiac arrhythmias, caffeinism, pheochromocytoma, seizure disorder disorders, migraine, central nervous system disorders, and medical reactions. The medical reactions may be to antihistamines, antiasthmatics, sympathomimetics, steroids, haloperidol and primiozide , selective serotonin reuptake inhibitors (SSRIs), antipsychotics (akatisia), and nonprescription preparations including diet pills and cold medicines (Bernstein and Kinlan. 1997).

### **PAST SURGICAL HISTORY:**

### **CHILDHOOD DISEASES/ ILLNESSES:**

### **ALLERGIES:**

### **FAMILY HISTORY:**

### **SOCIAL HISTORY:**

### **GENERALS:**

- ENERGY LEVELS
- DREAMS
- APPETITE
- FOOD LIKES/DISLIKES

- WEATHER LIKES/DISLIKES
- THIRST
- PERSPIRATION
- SEXUAL DESIRE/LIBIDO
- FEMALE MENSES
- STDs
- SUPPLEMENTS AND OTHER MEDICATIONS

**SYSTEM REVIEW:**

HEAD Headaches:

- Type?
- Location?
- Frequency?
- What makes it better or worse?
- Associating symptom?

EYES:

(Vision, glasses, contact lenses, pain, redness, double vision, cataracts)

EARS:

(Hearing problems, vertigo, tinnitus, earaches, infections, discharge).

NOSE AND SINNUSES:

(Pain congestion, nosebleed, frequency of colds, hayfever, loss of smell)

MOUTH AND THROAT:

(Swollen glands, pain or stiffness in the neck)

RESPIRATORY SYSTEM:

(Cough, sputum, haemoptysis, wheezing, asthma, bronchitis, TB)

CARDIAC SYSTEM:

(Chest pain or discomfort, hypertension, rheumatic fever, murmurs)

GASTROINTESTINAL SYSTEM:

(Heartburn, anorexia, nausea, vomiting, abdominal pains, haemorrhoids, constipation and diarrhoea)

URINARY SYSTEM:

(Infection, burning and pain on urination)

GENITAL SYSTEM:

Female—menses

--discharge/leucorrhoea

Male—impotence

--sexual desire

MUSCULOSKELETAL SYSTEM:

(Joint pain, stiffness, arthritis, gout, backache)

NEUROLOGICAL SYSTEM:

(Numbness, paralysis, weakness, fainting, tumor)

ENDOCRINE SYSTEM:

(Thyroid trouble, diabetes)

## APPENDIX - D

### ON EXAMINATION:

#### VITAL SIGNS:

- PULSE
- BLOOD PRESSURE
- RESPIRATORY RATE
- TEMPERATURE
- WEIGHT
- HEIGHT

#### GENERAL OBSERVATION:

(State of health, signs of distress, skin colour, and possible lesions, sexual development, posture, motor activity and gait, dress, grooming and hygiene, odours of the body and breath. Facial expression, note state of awareness and level of consciousness, listen to the patient's speech).

#### HEAD: Inspection and palpation

Note any –Deformities or lumps  
---Tenderness, other lesions

#### FACE: Inspection and palpation

Note facial expressions and contours, symmetry, involuntary movements, oedema, masses and facial pain.

#### EYES Inspection and palpation

Note position and alignment  
Note pupil size, shape, and equality.  
Note any redness, swelling, vascular pattern, and nodules.

#### NOSE AND PARANASAL SINUSES: Inspection and palpation

Examine external and internal surfaces  
Palpate the sinuses—Frontal sinus tenderness  
---Maxillary sinus tenderness  
Postnasal drip-----colour, odour, quantity, frequency

MOUTH AND PHARYNX:

***Lips-----colour, moisture, swelling***

Mouth---breath taste, pain, lesions

Teeth----caries, pain, abnormalities in shape, colour and position

Pharynx—tonsils, swellings, lesions, colour, ulceration, uvula

EARS: **Inspection and palpation**

Eardrum and canal—Discharge, foreign bodies, redness and swelling,  
Serum, colour and contour

---Handle of malleus

---Cone of light

---Perforations

NECK: **Inspection and palpation:**

Stiffness and pain

Thyroid gland

Tracheal deviation

JVP

Lymph nodes

THORAX **Inspection and palpation**

***Chest wall movement and shape***

Auscultation of heart and lungs

ABDOMEN

**Inspection** –Alignment, symmetry, scars, pulsations, lumps,  
enlargements ( ascites)

**Palpation**--- Pain, tenderness, guarding, spleen, liver, kidneys

**Auscultation**—Bowel sounds, pulsations

BACK

**Inspection----- *Symmetry of body***

Curvature and orientation of spine

Posture and restricted movements

UPPER AND LOWER LIMBS:

Hair distribution, colour, temperature, any lesion, any pain and muscle conditions

AXILLAE:

**Inspection**

**Palpation: 4 Areas---Central---Deep**

---Distal

----Pectoral/ anterior

----Subclavicular/ posterior

As well as -----Supraclavicular

-----Infraclavicular

### ***HOW TO TAKE HOMOEOPATHIC MEDICATION***

1. If you are taking powders- just open one end of the powder and tip it under your tongue, allow it to dissolve and **DO NOT TAKE IT WITH WATER.**
2. If you are taking pills or granules-**DO NOT TOUCH THEM WITH YOUR FINGERS.** The granules/ pills are dispensed in a glass vial with a plastic lid. Take off the lid and put the desired number of pills/ granules in the lid, place the pills/ granules directly under the tongue and allow them to dissolve.
3. Take your remedies **away from meals** at least ½ hour before a meal or one hour after. Avoid eating **MINT** before or after taking medication.
4. The remedies must be stored away from **camphor** (e.g. Vicks products), light, heat, and electromagnetic radiation (t.v.'s, computers, etc.).
5. Try to avoid the intake of coffee during your treatment.
6. Always take the powders in numerical order or otherwise as directed by your homoeopath.

*For any queries regarding your medication, please do not hesitate to contact me. Thank you...*



*Indlela yokuphuzwa kwemithi yakho ye-Homoeopathy*

1. Uma uphuza okusampushana-vele uvule icala elilodwa lokusampushana bese ukuthela ngaphansi kolimi, kulinde kuze kuncibilike futhi **UNGAKUPHUZI NAMANZI**.
2. Uma uphuza amaphilisi noma okusanhlamvana-**UNGAKUTHINTI NGEMINWE YAKHO**. Okusanhlamvana namaphilisi kufakwa ebhodloleni aliwutshumana elinesivalo sepulasitiki. Vula isivalo bese uthela inani elidingekile lamaphilisi noma ukusanhlamvana esivalweni, beka amaphilisi noma okusanhlamvana ngaphansi kolimi, bese ukulinda kuze kuncibilike.
3. Phuza imithi yakho kusasele isigamu sehora ngaphambi kokuba udle noma uyiphuze sekuphele ihora elilodwa usudlile. Gwema imithi.
4. Imithi mayigcinwe kude nezinto ezinjenge Vicks, Camphor, Zamburk, ukukhanya, ukushisa, futhi ungayibeki eduze nomabonakude, iwayilense, ikhompuyutha kanye nokunye.
5. Zama ukugwema ukuphuza ikhofi ngesikhathi uselashwa.
6. Njalo phuza okusampushana nganani elibekiwe, nangokulandelana kwezimbolo ezibhalwe ngaphandle kwemithi yakho, nangendlela oyalwe ngayo udokotela we Homoeopathy wakho.

Uma unemibuzo maqondana nemithi yakho, ungangabazi ukuxhumana nami, noma ukungithinta. *NGIYABONGA KAKHULU.*

**APPENDIX - F**

**Psychiatric Associates of Atlanta, LLC**

Twelve Piedmont Center, Suite 419, 3495 Piedmont Road, NE, Atlanta, GA 30305

404-495-5900 fax: 404-495-5901

www.atlantapsychiatry.com

**David Lipsig, M.D.**

**Matthew Norman, M.D.**

**HAMILTON ANXIETY RATING SCALE (HAM-A)**

Classification of symptoms: 0 - absent; 1 - mild; 2 - moderate; 3 - severe; 4 - incapacitating.

HAM-A score level of anxiety: < 17 mild; 18 - 24 mild to moderate; 25 - 30 moderate to severe.

Symptoms

Date: \_\_\_\_\_

- |   |           |   |           |
|---|-----------|---|-----------|
| 1. Anxious mood<br>• worries<br>• anticipates worst   | 0 1 2 3 4 | 10. Respiratory Symptoms<br>• chest pressure<br>• choking sensation<br>• shortness of breath            | 0 1 2 3 4 |
| 2. Tension<br>• startles<br>• cries easily<br>• restless<br>• trembling                                     | 0 1 2 3 4 | 11. Gastrointestinal Symptoms<br>• dysphagia<br>• nausea or vomiting<br>• constipation<br>• weight loss | 0 1 2 3 4 |
| 3. Fears<br>• fear of the dark<br>• fear of strangers<br>• fear of being alone<br>• fear of animal          | 0 1 2 3 4 | 12. Genitourinary Symptoms<br>• urinary frequency or urgency<br>• dysmenorrhea<br>• impotence           | 0 1 2 3 4 |
| 4. Insomnia<br>• difficulty falling asleep or staying asleep<br>• difficulty with nightmares                | 0 1 2 3 4 | 13. Autonomic Symptoms<br>• dry mouth<br>• flushing<br>• pallor<br>• sweating                           | 0 1 2 3 4 |
| 5. Intellectual<br>• poor concentration<br>• memory impairment  | 0 1 2 3 4 | 14. Behavior at Interview<br>• fidgets<br>• tremor<br>• paces   | 0 1 2 3 4 |
| 6. Depressed Mood<br>• decreased interest in activities<br>• anhedonia<br>• insomnia                        | 0 1 2 3 4 |   |           |
| 7. Somatic complaints - Muscular<br>• muscle aches or pains<br>• bruxism                                    | 0 1 2 3 4 |   |           |
| 8. Somatic complaints - Sensory<br>• tinnitus<br>• blurred vision   | 0 1 2 3 4 |   |           |
| 9. Cardiovascular Symptoms<br>• tachycardia<br>• palpitations<br>• chest pain<br>• sensory of feeling faint | 0 1 2 3 4 |   |           |

TOTAL SCORE: \_\_\_\_\_

Rater's signature: \_\_\_\_\_

## APPENDIX - G

# BECK ANXIETY INVENTORY

Below is a list of common symptoms of anxiety. Please carefully read each item in the list. Indicate how much you have been bothered by that symptom during the past month, including today, by circulating the number in the responding space in the column next to each symptom.

	Not at all.	Mildly but it didn't bother me much.	Moderately - it wasn't pleasant at times.	Severely- it bothered me a lot.
1. Numbness or tingling	0	1	2	3
2. Feeling hot	0	1	2	3
3. Wobbliness in legs	0	1	2	3
4. Unable to relax	0	1	2	3
5. Fear of worst happening	0	1	2	3
6. Dizzy or lightheaded	0	1	2	3
7. Heart pounding/racing	0	1	2	3
8 Unsteady	0	1	2	3
9. Terrified or afraid	0	1	2	3
10. Nervous	0	1	2	3
11. Feeling of choking	0	1	2	3

<b>12. Hands trembling</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>
<b>13. Shaky/unsteady</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>
<b>14. Fear of losing control</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>
<b>15. Difficulty in breathing</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>
<b>16. Fear of dying</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>
<b>17. Scared</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>
<b>18. Indigestion</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>
<b>19. Faint/lightheaded</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>
<b>20. Face flushed</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>
<b>21. Hot/cold sweats</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>
<b>Column Sum</b>				

**Scoring- Sum each column. Then sum the totals to achieve a grand score. Write that score here-----**

## APPENDIX - H



### PATIENT PERCEPTION QUESTIONNAIRE

#### **DURBAN INSTITUTE OF TECHNOLOGY**

#### **DEPARTMENT OF HOMOEOPATHY**

#### **RESEARCH QUESTIONS:**

**TO: PATIENTS** (WITH GENERALIZED ANXIETY DISORDER)

**The answer to these questions in this questionnaire will be regarded as strictly CONFIDENTIAL and will be used for research purposes only.**

#### INSTRUCTIONS:

- a) Please answer the questions as objectively and as accurate as possible.
- b) Please read each question carefully before answering it.
- c) Please ensure that you answer all the questions.
- d) If you have any queries, please ask for assistance from the researcher conducting the questionnaire.

#### **1. Please rate the current severity of your Generalized Anxiety Disorder by circulating the appropriate number.**

- WORRY ----- 0 Absent-----1 Mild-----2 Moderate-----3 Severe-----4 Very
- ANXIETY-----0 Absent-----1 Mild-----2 Moderate-----3 Severe-----4 Very
- FATIGUE-----0 Absent-----1 Mild-----2 Moderate-----3 Severe-----4 Very

- IRRITABILITY---0 Absent----1 Mild-----2 Moderate-----3 Severe-----4 Very
- SLEEP  
DISTURBANCE----0 Absent----1 Mild---2 Moderate-----3 Severe-----4 Very
- MUCSLE  
TENSION -----0 Absent-----1 Mild-----2 Moderate -----3 Severe-----4 Very
- DIFFICULTY  
IN CONCERNTRATION -----0 Absent-----1 Mild-----2 Moderate-----  
3 Severe-----4 Very

**2. How satisfied/ dissatisfied are you with your current condition (GAD).**

*Very Satisfied* \_\_\_\_\_ *Moderate Satisfied* \_\_\_\_\_ *Very Satisfied* \_\_\_\_\_  
**1**                    **2**                    **3**                    **4**                    **5**

**3. To what extent do you consider your anxiety disorder to interfere with your daily functioning (daytime fatigue, restlessness, ability to function at work/ school, concentration, mood, irritability, muscle tension, sleep disturbance)?**

*Not at all* \_\_\_\_\_ *A little* \_\_\_\_\_ *Somewhat* \_\_\_\_\_ *Much* \_\_\_\_\_ *Very Much*  
**1**                    **2**                    **3**                    **4**                    **5**

**4. How noticeable to others do you think your anxiety disorder is in terms of impairing the quality of your life?**

Not at all                    A little                    Somewhat                    Much                    Very Muc  
**1**                    **2**                    **3**                    **4**                    **5**

APPENDIX - I



**The Randomization Chart**

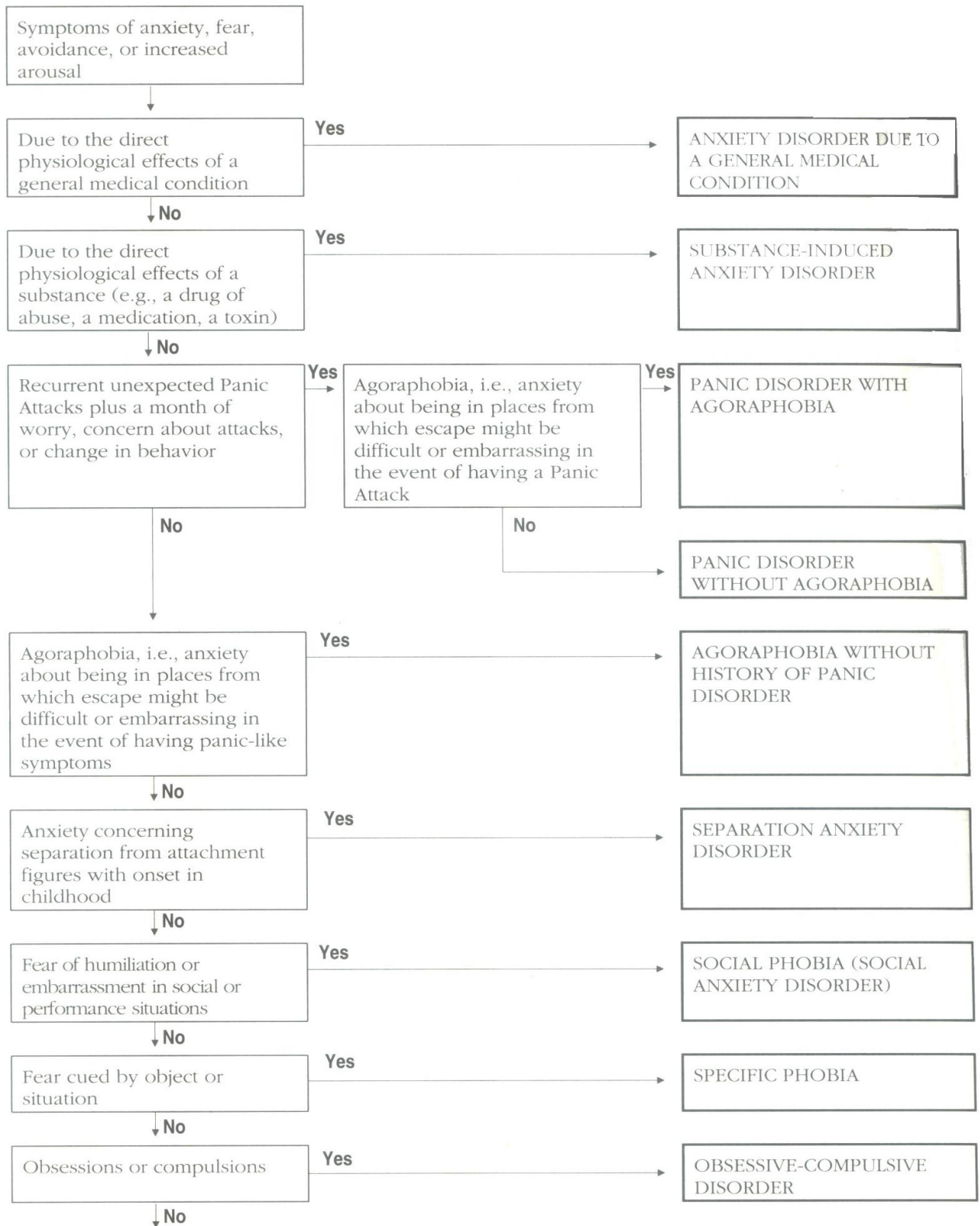
Refer 3.2.3

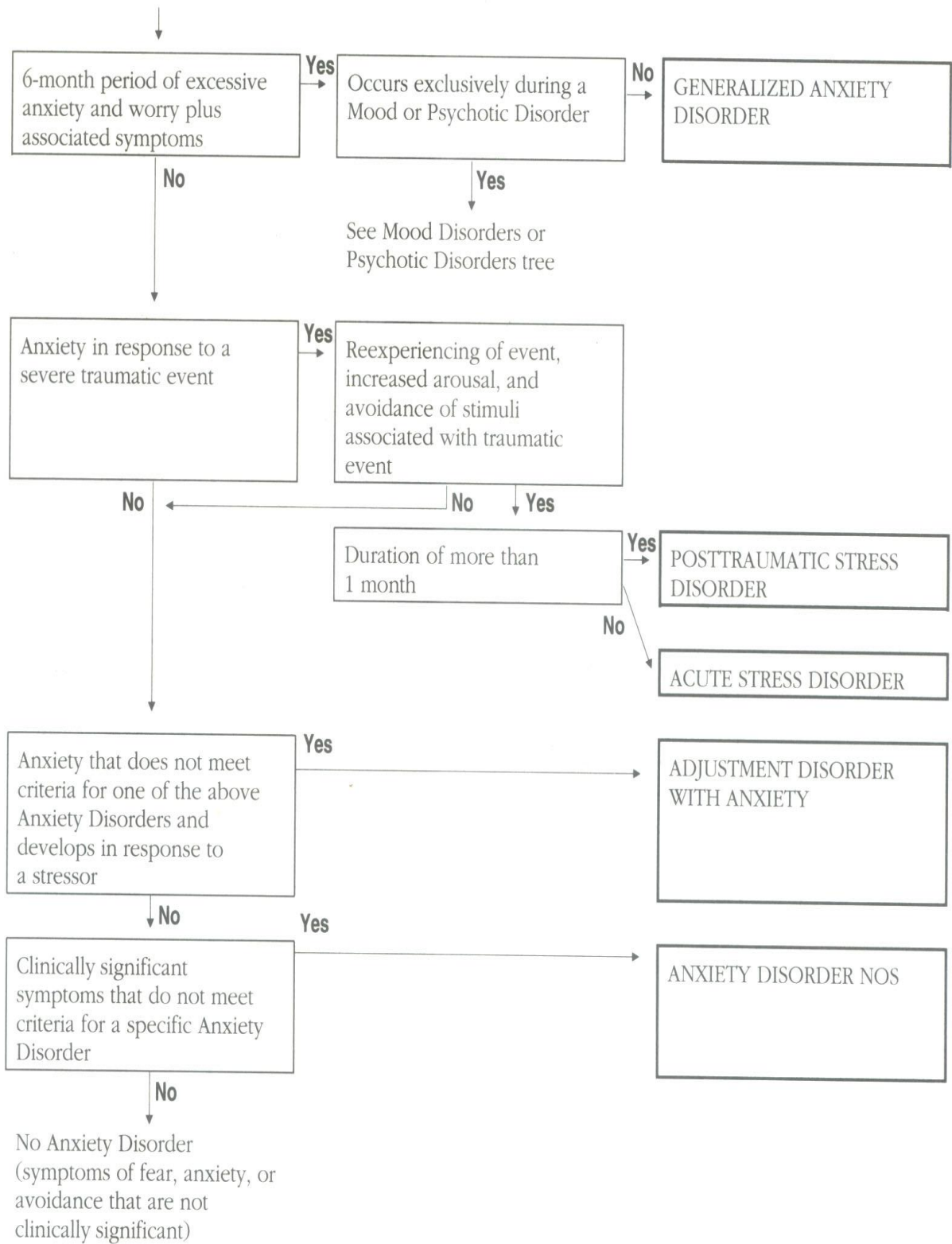
Patient no.	Simillimum Group	Counseling Group	Placebo Group
1			x
2		x	
3	x		
4			x
5			x
6	x		
7			x
8		x	
9			x
10	x		
11		x	
12			x
13			x
14		x	
15	x		
16			x
17	x		
18		x	
19	x		
20	x		
21			x
22	x		
23			x
24		x	
25			x
26			x
27			x
28	x		
29	x		

<b>30</b>		<b>x</b>	
<b>31</b>		<b>x</b>	
<b>32</b>		<b>x</b>	
<b>33</b>		<b>x</b>	
<b>34</b>	<b>x</b>		
<b>Total no.</b>	<b>11</b>	<b>10</b>	<b>13</b>

**APPENDIX - J**

**DIFFERENTIAL DIAGNOSIS OF ANXIETY DISORDERS**





## APPENDIX - K

### **METHOD 10. Granules (Globuli (British Homoeopathic Association. (1991)**

Preparations made by Method 10 are granules (globuli). They are produced by transferring a dilution to sucrose granules (size 3: 110 - 130 granules weigh 1 g) by moistening 100 parts of sucrose granules evenly with 1 part of dilution. The ethanol content of the dilution should be not less than 60 per cent. If this is not the case, it will be necessary to go against Methods 1 to 4b and produce the final potentization of the decimal or centesimal dilution which is to be used with ethanol 62 per cent.

Following impregnation in a closed vessel, the granules (globuli) are air-dried. They are labeled with the dilution stage of the dilution used to impregnate them. The following granule sizes may be used in special cases:

Size 1	470-530	granules weigh 1g
Size 2	220-280	granules weigh 1g
Size 3	110-130	granules weigh 1g
Size 4	70- 90	granules weigh 1g
Size 5	40- 50	granules weigh 1g
Size 6	22- 28	granules weigh 1g
Size 7	10	granules weigh approx. 1g
Size 8	5	granules weigh approx. 1g
Size 9	3	granules weigh approx. 1g
Size 10	2	granules weigh approx. 1g

**DIAGNOSTIC CRITERIA FOR 300.02 GENERALIZED**  
**ANXIETY DISORDER**

- A. Excessive anxiety and worry (apprehensive expectation), occurring more days than not for at least 6 months, about a number of events or activities (such as work or school performance).
- B. The person finds it difficult to control the worry.
- C. The anxiety and worry are associated with three (or more) of the following six symptoms ( with at least some symptoms present for more days for the past 6 months):

NOTE: Only one item is required in children.

- Restlessness or feeling keyed up or on edge;
- Being easily fatigued;
- Difficulty concentrating or mind going blank;
- Irritability;
- Muscle tension;
- Sleep disturbance difficulty falling or staying asleep or restless; unsatisfying sleep).

**D. The focus of the anxiety and worry is not confined to features of an AXIS I Disorder, e.g., the anxiety or worry is not about having a panic attack (as in Panic Disorder ), being embarrassed in public (as in Social Phobia), being contaminated (as in Obsessive Compulsive Disorder), being away from home or close relatives (as in Separation Anxiety Disorder), gaining weight (as in Anorexia Nervosa), having multiple physical complaints (as in Somatisation Disorder), or having serious illness(as in Hypochondriasis), and the anxiety and worry do not occur exclusively during Post-traumatic Stress Disorder.**

**E. The disturbance is not due to the direct physiological effects of a substance (e.g. a drug of abuse, a medication) or general medical condition (e.g. hyperthyroidism) and does not occur exclusively during a Mood Disorder, a Psychotic Disorder, or a Passive Developmental Disorder**

**APPENDIX – M**

*Referral Letter*

Date of first appointment .....

Patient's name.....

Age.....Occupation.....

Thank you for seeing this patient.

Main complaint / Diagnosis:

**Generalized anxiety disorder (GAD).**

Medication

Homeopathic medication has been prescribed for this patient, which has to be taken at the same time as psychological counseling.

Conclusion

This patient is being referred to you for psychological counseling (Cognitive and behavioral therapy)

Yours Sincerely

Jabulile Ngobese  
6<sup>th</sup> year Research student

Dr. D. Naude  
Research Supervisor

**Dr. Frida Rundell**

PhD. (Community Psychology)  
(B.A. Hon (Psy) ; M. Ed Psy.)

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## APPENDIX – N



### *DO YOU SUFFER FROM EXTREME ANXIETY & WORRY???*

*Are you experiencing the following signs & symptoms???*

- *Difficulty in controlling anxiety & worry.*
- *Muscular aches & pains, tiredness, stomach cramps, indigestion, lack of concentration, impatience, & irritability.*
- *Restlessness, sleep disturbance or difficulty in falling asleep.*

*You might be suffering from Generalized Anxiety Disorder (GAD).*

The Durban Institute of Technology, Department of Homoeopathy is recruiting individuals who suffer from Extreme Anxiety & Worry, who are willing to participate in a Master's Degree Research project.

Participants must be between 18 & 60 years.

*Treatment is Free*

*For further information contact:*

*083 526 3746 (Jabu)*

**APPENDIX – 0**



Follow up Consultation

**MAIN COMPLAINT:**

**Aggravations, amelioration or no change**

**Any changes since the remedy**

**NEW SYMPTOMS THAT HAVE APPEARED SINCE THE REMEDY**

**Is this an old symptom that has reappeared or is it a new symptom altogether?**

**If it is an old symptom, when did it start, is it as bad as before, or not, and is it affecting the patient adversely?**

## **OTHER QUESTIONS TO ASK**

### **ENERGY:**

Any change, and if there is how, when and how much?

Level of exercise - more active, less active or the same.

### **SLEEP**

Quality

Quantity

Position

Dreams

Other

### **APPETITE**

Change

New cravings or aversions

New desires

Thirst

### **OTHER CHANGES**

**MENTALS**