The Effect of a Homoeopathic Remedy, *Passiflora incarnata* Ø on Insomnia

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DECLARATION

I, Sunaina Amiraj- Surujparsad, declare that this dissertation is my own work. It is being submitted for the degree of Masters of Technology: Homoeopathy at the University of Johannesburg. It has not been submitted before for any degree or diploma at this or any other tertiary institution. This study was approved and passed by the Higher Degrees Committee on the 18 August 2006. The ethical clearance number is 44/06.

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ABSTRACT

The term insomnia is derived from the Latin words *in,* meaning "not", and *somus,* meaning "sleep". Thus insomnia means "the inability to sleep" (Thorpy and Yager, 2001). Patients perceive that their sleep is inadequate or abnormal. The symptoms include: difficulty initiating sleep, frequent awakenings from sleep, a short sleep time and non restorative sleep (Kryger *et al*, 1989).

Passiflora incarnata Ø is a remedy that is indicated in the Homoeopathic Materia Medica for treating insomnia, when the type of sleeplessness which occurs is an inability to fall asleep due to mental anxiety, stress, or from nervous excitement.

This study aimed to ascertain the efficacy of the homoeopathic remedy, *Passiflora incarnata* Ø, on difficulty in falling asleep. The quality of sleep was assessed in terms of duration of sleep, degree of feeling refreshed upon waking, and satisfaction with sleep.

This study was a double blind placebo controlled study with a sample of thirty participants, males and females between the ages of 19 and 49. Participants were recruited by means of advertisements in local newspapers, emails and pamphlets that were distributed in and around the University of Johannesburg, the health clinic, health shops, shopping malls, residential areas and at the Sleep Unit at the University of Witwatersrand. Participants, who met the inclusion criteria and completed the initial questionnaire (Appendix B), were required to sign the consent form (Appendix A). Participants were randomly divided into two groups of fifteen; one group received *Passiflora incarnata* Ø, and the other group received the placebo. The groups were instructed to dilute fifty drops of the medication in 20ml (4 tsp) of water. The medication was to be taken orally twenty minutes before going to bed, for a period of four weeks. Neither the participant nor the researcher was aware of what they had received. Furthermore participants were given a sleep diary (Appendix C) at the initial consultation which they were required to complete every morning. An appointment was made with the participant for a follow up visit on weeks two and four. At each follow up visit the sleep

diary (Appendix C) was checked to encourage compliance and a case history (Appendix D) was taken. The participants' blood pressure, pulse rate, respiratory rate and temperature were taken to monitor their wellbeing.

The data obtained from the initial questionnaire and the sleep diary was statistically analysed using the General Linear Model: Repeated Measures, Mann- Whitney test (non-parametric test), Cross Tabulation, Fisher's exact test and Regression analysis.

Statistical analysis showed no significant differences in the P- values between the Passiflora and placebo groups. Therefore the null hypothesis was accepted. However, within the Passiflora group, the males did have a consistently higher average in the number of hours slept over the 4 week period and they also noticed more of an improvement in their sleeping pattern compared to the females taking the medication. With regards to the satisfaction of sleep over the 4 weeks, the males, taking *Passiflora incarnata* Ø had more satisfaction with their sleep. The overall P- value was P= 0,046. This was statistically significant. Preliminary findings suggest that the homoeopathic complex *Passiflora incarnata* Ø may be more effective for insomnia in males than in females.

''All glories to Sri Radha Krsna, who is most merciful''

To my parents for always holding my hand through every
moment of my life and giving me, love
wisdom and strength...

To my husband for his love, encouragement,
support and prayers, during
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CHAPTER ONE:

INTRODUCTION

1.1 General Introduction

Problem Statement

Insomnia is defined as a complaint regarding the quality, quantity or timing of sleep for at least 1 month. Sleep is divided into Rapid eye movement sleep (REM) and non REM sleep. Non REM sleep has 4 stages, each progressively deeper. Stages 3 and 4, which is the deep restorative sleep, is also called the slow wave sleep. Research studies define insomnia as sleep latency, which is time taken to fall asleep that is greater than 30 minutes, sleep efficiency, which is time asleep or time in bed that is less than 85%, or sleep disturbance more than 3 times a week (Ringdahl *et al*, 2004).

Insomnia is not simply measured by the number of hours one sleeps, as people's needs vary. Some insomniacs sleep longer than 'normal' sleepers, but do not feel as refreshed as a 'normal' sleeper would. True insomnia affects one's daily life and performance. The true test to determine if a person is suffering from insomnia is, to determine if one consistently feels sleepy, tired and irritable throughout the day, and if one's memory, concentration and ability to work are affected (Courtenay, 1990).

The allopathic treatment of insomnia includes several classes of medication: benzodiazepines, barbiturates, non-benzodiazepine hypnotics, anti-depressants and over the counter sleep aids (Morin, 1993; Ringdahl *et al*, 2004). The above classes of medication have many side effects, some of which include; drowsiness, over sedation, restlessness and they are addictive (SAMF, 2003).

Passiflora incarnata Ø is a homoeopathic remedy that is used in treating insomnia and its symptoms. It is given in doses of from 30 to 60 drops, and this will increase sleep if

mental irritation is the cause of the wakefulness (Rawat, 2000). The researcher therefore postulates that the homoeopathic medication may provide an alternate form of treatment for insomnia.

1.2 Aim of the Study

This study aimed to ascertain the efficacy of the homoeopathic remedy, *Passiflora incarnata* Ø, on the difficulty in falling asleep. The quality of sleep was assessed in terms of duration of sleep, the degree of feeling refreshed upon waking, satisfaction with sleep and the change in sleep pattern.

1.3 Objectives

The objective of the study is to determine if *Passiflora incarnata* Ø reduces or alleviates insomnia and its symptoms and can therefore be used as an alternate form of treatment.

1.4 Hypotheses

a) Hypothesis

The oral administration of *Passiflora incarnata* Ø is effective in the treatment of insomnia.

b) Null Hypothesis

The oral administration of *Passiflora incarnata* Ø is not effective in the treatment of insomnia.

A P-value of less than P= 0.05 was considered significant, and greater than P= 0.05 was considered not significant. If there is no significant difference between the experimental and control group, the null hypothesis will be accepted.

If participants in the experimental group show a significant alleviation of symptoms, the hypothesis can not be rejected.

1.5 Assumptions

1.5.1 Assumption one

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

1.5.2 Assumption two

It is assumed that the patients will fill out their sleep diaries accurately and truthfully, for the duration of the study.

1.5.3 Assumption three

It is assumed that the patients will refrain from using any medication, as far as possible, that they would usually take, for the duration of the study. If they do take any medication for insomnia it should not be more than 3 times and it would have to be recorded in their sleep diary on the days it was taken.

1.5.4 Assumption four

It is assumed that the medication has been prepared in accordance with the homeopathic pharmacopoeias.

CHAPTER TWO:

LITERATURE REVIEW

2.1 Normal sleep pattern

The need for an adequate quantity and quality of sleep is a biological drive that is similar to hunger and thirst that must be met in order for people to function appropriately in daily life. Sleep is divided into two separate stages; non-rapid eye movement sleep (NREM), and rapid eye movement sleep (REM). NREM is further divided into four stages and accounts for 75-80% of total sleep. REM is made up of 20-25% total sleep. Stage one of NREM sleep, which consists of 2-5% of consolidated sleep, is characterized by a low threshold for arousal. This stage occurs at sleep onset and during stage transitions. Stage two of NREM continues for 10-25 minutes after stage one and has a higher threshold for arousal. Deep sleep occurs at stage 3 and 4 of NREM sleep, and makes up 13-23% of sleep time. During a REM period, rapid eye movements are observed, as well as an absence of muscle tone. The average period for alternating between NREM- REM is 90-110 minutes, occurring in 4 to 6 episodes during sleep. When the sleep period is shortened, or an inadequate amount of time is spent in stages three and four, NREM or REM sleep, the structure of sleep is disrupted. Difficulties with daytime performance or unwanted sleepiness during wake time are often manifestations of sleep disruption or insufficient sleep (Gyllenhaal *et al*, 2000).

2.2 Definition of Insomnia

The term insomnia is derived from the Latin word *in,* meaning "not", and *somus,* meaning "sleep". Thus insomnia means "the inability to sleep" (Thorpy and Yager, 2001). Patients perceive that their sleep is inadequate or abnormal. The symptoms include: difficulty initiating sleep, frequent awakenings from sleep, a short sleep time and non restorative sleep (Kryger *et al*, 1989).

2.3 Prevalence of insomnia

Insomnia is the most common sleep disorder reported in the general population, with an estimated 10-35% being affected (Sutton *et al*, 2001). Between 30-40% of adults indicate some level of insomnia within any given year. About 10-15% indicate that their insomnia is chronic, severe or both. The prevalence of insomnia increases with age and is more common in women. An increased prevalence of insomnia has also been associated with psychological disturbances, and a lower socioeconomic status. These two factors increase the likelihood of insomnia complaints and appear to be related, because mental health disorders are more prevalent in those of lower socioeconomic status. Noise, crowding and other conditions associated with disadvantaged social environments, may also contribute to sleep disturbance (Walsh *et al*, 1999).

2.4 Structure of insomnia

Insomnia can be classified as either acute insomnia or chronic insomnia.

2.4.1 Acute insomnia:

It usually presents with a history of a few days or weeks. Acute insomnia has many different causes including: life stress, brief illness, hypnotic withdrawal or temporary sleep deprivation. Recovery is usually rapid after a period of maximum sleep disruption of two to three weeks. Acute insomnia as a result of change of environment, emotional crisis, a new baby, illness or bereavement, is experienced by everyone several times a year. This sleep disruption can take any form, depending on the age, previous sleep habit and personality of the person (Walsh *et al*, 1999; Nichols *et al*, 2007).

2.4.2 Chronic insomnia:

Chronic insomnia may be life long. It is usually a consequence of old age, medical, behavioural or psychiatric problems. Chronic insomnia is further broken down into three classes:

2.4.2.1 Primary chronic insomnia-

This type of insomnia is characterised by unexplained, life- long, fragmented inadequate sleep (Walsh *et al*, 1999; Nichols *et al*, 2007).

2.4.2.2 Secondary chronic insomnia-

This class is normally associated with: (Walsh *et al*, 1999; Nichols *et al*, 2007).

- Medical problems
- Physiological problems
- Psychological problems
- Psychiatric problems
- Drugs
- Cyclical causes

2.4.2.3 Chronic insomnia due to abnormal sleep control-

In this class sleep difficulty is part of the sleep disorder. Some disorders that fall under this class are: parasomnias, narcolepsy and obstructive sleep apnoea (Walsh *et al*, 1999; Nichols *et al*, 2007). Parasomnia is a disease condition that produces unusual behaviours that occurs during sleep. People that experience parasomnias experience it in one of the following ways; either as brief involuntary jerking of the arms or the entire body. This is commonly referred to as restless legs syndrome. Sufferers can experience brief hallucinations when falling asleep or waking up. Nightmares, sleep walking and night terrors also form part of parasomnias (Heckelman and Maryadele, 2003). Narcolepsy is a disease that produces daytime sleepiness. The person suffering from this sleeps normally but also falls asleep at inopportune moments during the day. Sleep apnoea occurs in people who have an obstruction at the back of their throats. As their throat relaxes with sleep, their breathing is cut off and the oxygen levels in their blood drops. As a result, sleep apnoea sufferers never get into the deep stage of sleep, and are tired throughout the day (Courtenay, 1990).

2.5 Aetiology

The causes of insomnia can be divided into psychological factors, social factors, physiological factors or medical factors. Common psychological causes of insomnia are

anxiety, other minor worries or even major psychological stress. Insomnia could also be a consequence of depression. Social problems that can cause insomnia include work situations or marital problems. Physiological factors contributing to insomnia in some individuals manifests as a malfunction in sleep cycle of unknown aetiology. Some medical factors that could cause insomnia include parasomnias, restless legs syndrome and obstructive sleep apnoea (Shapiro *et al*, 1994; Ayalon *et al*, 2004).

2.6 Symptoms of Insomnia

Mild insomnia occurs at least once or twice a week. The individual receives an insufficient amount of sleep, or does not feel rested after the usual sleep period. This individual will experience irritability, some daytime anxiety or fatigue, tiredness and a feeling of general restlessness. Moderate insomnia occurs more than twice a week. There are always sensations of restlessness, mild anxiety, tiredness, daytime fatigue and also irritability. Severe insomnia occurs nightly. There is a sense of not being fully alert, some daytime fatigue and tiredness. Irritability is always present as well as some anxiety. Headaches are also a common finding in insomnia patients (Shapiro *et al*, 1994; Roth *et al*, 2007).

2.7 Treatment of Insomnia

2.7.1 Allopathic treatment

Pharmacologic symptomatic suppression of insomnia symptoms in short-term insomnia with short acting hypnotics is considered beneficial because this treatment decreases the likelihood of perpetuation of sleep disturbances (Olejniczak and Fisch, 2003). Several classes of medication are used in the management of insomnia: benzodiazepines, barbiturates, non-benzodiazepine hypnotics, anti-depressants and over the counter sleep aids (Morin, 1993).

- **Benzodiazepines** – These have sedative and hypnotic properties. They are used frequently for insomnia associated with anxiety disorders. Most of these

medications act as muscle relaxants and also have a sleep inducing effect (Shapiro *et al*, 1994; Morin, 1993). The side effects of the above mentioned drug group most frequently are, drowsiness and over sedation, especially with high doses and in elderly patients (SAMF, 2003).

- **Non-Benzodiazepine hypnotics** – These have been found to be effective in decreasing sleep onset latency, but not in decreasing the number or duration of awakenings (Shapiro *et al*, 1994; Morin, 1993). The side effects of these drugs are; that they are addictive, cause daytime somnolence and they can cause rebound insomnia on cessation (Longmore *et al*, 2001).
- **Anti-depressants** – These drugs are used to treat depression and not insomnia. They help to reduce the depression and thereby the insomnia in depressed people (Shapiro *et al*, 1994; Morin, 1993). A clinical trial was done using a drug called trazodone, which is a form of antidepressant. There were many adverse effects including drowsiness, dizziness, dry mouth, nausea, vomiting, headache, hypertension and blurred vision. It should be noted that the dropout rate in this study was very high. Approximately 25%-50% of discontinuations were due to the adverse effects (Mendelson, 2005). There are a variety of antidepressant medications available on the market and some of the side effects include; epileptic seizures, sedation, excessive sweating, muscle tremors, restlessness and weakness (SAMF, 2003).
- **Over the counter sleep aids** – The active ingredient in these drugs is antihistamine. Thus since antihistamines cause drowsiness, people use them to promote sleep at night (Morin, 1993). With these medications the "hangover" effect may be quite remarkable. Over the counter sleeping aids are not recommended for children, and should be used with caution by the elderly (SAMF, 2003).

2.8 Natural approach to insomnia

The use of complementary and alternative therapies not commonly taught in medical schools, or available in hospitals, has increased substantially world wide (Gyllenhaal *et al*, 2000).

2.8.1 Nutrients used in the treatment of insomnia

Calcium is used in the treatment of insomnia, because it has a calming effect. Magnesium is needed to balance the calcium and also causes the muscles to relax (Balch and Balch, 2000). Melatonin is a hormone that the pineal gland produces each night to help us sleep. Melatonin is highest during adolescence and begins to gradually decline in the mid twenties. It has been proposed that a decrease in melatonin levels may increase the incidence of insomnia. There have been many studies done that have examined the effectiveness of melatonin as a potential treatment for insomnia (Rodgers *et al*, 2003). Vitamin B complex is also useful because it helps promote a restful state. Panthothenic acid is good for relieving stress. Inositol is also useful because it enhances REM sleep (Balch and Balch, 2000).

2.8.2 Sleep hygiene

This advice concerns the improvement of sleep 'hygiene' by non drug methods, and is recommended in many sleep disorder centres. The advantage of using hypnotics is that they have an immediate effect, but the repeated use of the hypnotic would reduce this effect. Improving sleep hygiene requires more of an effort. It may take several days, or even weeks to improve sleep, but the result is long lasting, more rewarding and has no side effects (Horne, 1990). In the Principles and Practice of Sleep Medicine, the following recommendations have been with regards to sleep hygiene (Kryger *et al*, 2000). The instructions can be broken down into the following categories:

a) Homeostatic drive for sleep:

This refers to the ability of an individual to maintain an internal equilibrium or a balance by adjusting ones physiological processes in order to achieve a normal sleeping pattern.

- Avoid naps, except for a brief 10-15 minute nap after 8 hours of being awake.
- Restrict sleep period to the average number of hours you slept per night in the preceding week. Quality of sleep is important. Too much time in bed can decrease the quality of the subsequent night's sleep.
- Get regular exercise, at least 40 minutes of activity that causes sweating, every day.
- Take a hot bath to raise body temperature within 2 hours before going to bed (Kryger *et al*, 2000).

b) Circadian Factors:

The circadian rhythm corresponds well with to the sleep-wake cycle and is synchronized to the external environment in response to changes across the 24 hour day. Daily light and dark cycles entrain the circadian system, which signals the appropriate time for activity and for rest (Reid *et al*, 2004).

- Rise at a regular time 7 days a week.
- Do not get exposed to bright light when waking up at night (Kryger *et al*, 2000).

c) Drug Factors:

This refers to taking any kind of stimulus, from caffeine to alcoholic beverages that may cause a disruption in ones sleeping pattern.

- Do not smoke to get one back to sleep.
- Do not smoke after 7 in the evening, or give up smoking entirely.
- Avoid caffeine for a 4 week trial period.
- Have only light to moderate alcoholic beverages. Alcohol can cause sleep fragmentation over the 2nd half of the sleep period (Kryger *et al*, 2000).

d) Arousal in Sleep Setting:

These are suggestions informing an individual that one should keep the bedroom free from any stress which could affect the sleeping pattern, as well as in avoiding certain activities prior to going to bed.

- Avoid strenuous exercise after 6 in the evening.
- Do not eat or drink heavily 3 hours before going to bed.
- Keep the room dark, quiet, well ventilated and at a comfortable temperature throughout the night.
- Practice a bedtime ritual, for example; reading before putting the lights out.
- Use stress management during the day.
- Avoid unfamiliar sleep environments.
- Use your bedroom only for sleep; do not work or do other activities that may lead to prolonged arousal (Kryger *et al*, 2000).

2.9 Homoeopathic treatment

2.9.1 Introduction

Homoeopathy is a gentle and effective form of treatment that is used for many conditions, illnesses and diseases. It is holistic in nature which means that the entire person is considered, as well as the specific problem or illness, in determining a treatment. The medicines used in homoeopathy are minute doses of natural substances which have been taken either from the plant, animal or mineral kingdom (Dannheisser and Edwards, 1988).

Homoeopathy is a therapeutic medical system which must be considered to have been part of the medical sciences, from the very beginning of the history of medicine. It is a science; an art of preventing and treating disease. In the 1st two Aphorisms in the Organon of Medicine, Hahnemann states that "The physician's high and only mission is to restore the sick to health or to cure." He also described the highest ideal of cure to be "...a rapid, gentle and permanent restoration of health, or removal and annihilation of the disease in its whole extent, in the shortest most reliable and most harmless way, on easily comprehensive principles" (Eizayaga, 1991)

2.9.2 Samuel Hahnemann

Christian Friederich Samuel Hahnemann, a German physician in the late 18th century, is considered to be the 'Father of Homoeopathy' (Lockie, 2000). He was well acquainted with the classical ideas of curing. However Hahnemann became disillusioned with the medicine of his time. Other methods were used for those who were ill, for example: purgatives, emetics, and blood letting. He found that these therapies lacked a logical basis and had no scientific proof. Being very honest, Hahnemann decided to give up his practice as a physician, and translate books to support his family (Eizayaga, 1991).

While Hahnemann was translating 'Treatise on the Materia Medica' by William Cullen, he found that he did not agree with the author on the action of Cinchona. According to William Cullen, Cinchona was used to treat intermittent fever in malaria, due to its astringent properties. Hahnemann decided to dose himself with quinine and found that he developed symptoms that were similar in nature to malaria. These symptoms developed when he took the quinine and disappeared when he stopped. Hahnemann concluded that if a remedy given to a healthy person could provoke certain symptoms, it would be capable of curing similar symptoms in an unhealthy person. Hahnemann continued testing other substances on himself as well as other healthy individuals. The tests were carried out in a controlled environment. Little by little Hahnemann accumulated the medical wisdom today called the Materia Medica. It was from the above testing that the Law of Similars was derived (Eizayaga, 1991).

2.9.3 Principles of Homoeopathy

Homoeopathy is governed by principles. "It is a therapeutic method which clinically applies the Law of Similars and which uses medicinal substances in weak or Infinitesimal Doses" (Jouanny, 1993). The main principle formulated by Hahnemann is *'Similia Similibus Curentur'*, meaning: *let likes be cured by likes* (Eizayaga, 1991). The Law of Similars is the formulation of a physiological state of things, which had already been observed 25 centuries ago by Hippocrates. Hahnemann under took a lot of

experimentation, and he was able to observe that the hypothesis that he initially formulated was proved to be consistently true. Therefore the Law of Similars is a general biological law (Jouanny, 1993). The Law of Similars states that any substance that can produce a totality of symptoms in a healthy individual, can cure the totality of symptoms in a sick individual (Vithoulkas, 1980).

Another principle in Homoeopathy is known as the Principle of Minimum Dose. Hahnemann states in Aphorism 68 of the Organon that minute doses of simple, proven medicines are used to cure disease through the principle of like cures like. The term 'simple medicine' refers to medicine that is not mixed with any medicinal substances. These doses are so small that they don't cause any pain or debilitation to the patient (Hahnemann, 1982).

2.9.4 Individualization of the patient

The human organism works as a totality, whether it is performing its normal functions or defending itself, in the case of a disease condition (Vithoulkas, 1980). When treating a patient homoeopathically, each patient is treated as an individual. This means that all mental, emotional and physical aspects are taken into account. This is referred to as the individualization of treatment. This means that the totality of symptoms will provide the practitioner with enough information, to select the appropriate remedy for the condition (Jouanny, 1993). There are some remedies used in homoeopathy that are well known for their affinity or sphere of action within certain systems of the body, or it used for the relief of a particular condition. An example of a well known remedy used is *Arnica*. It is used more as a specific as opposed to being individualised (Gleeson, 2008). As indicated in the homoeopathic materia medica, *Arnica*, has the ability in relieving the after effects of an accident especially when bruising is involved (Boericke, 2000).

2.9.5 Preparation of Homoeopathic Medicines

Homoeopathic remedies are derived from plant, animal and mineral sources. Depending on their natural state, they can be prepared in different ways. Plant and animal material may be used whole or chopped, depending on their size and density (Lockie, 2000).

Preparations of drugs are made in liquid or solid form, in all possible pharmaceutical dosage forms, except for injections. Substances that are soluble in the liquid vehicles, such as plant or animal extracts, are made either into tinctures or solutions. For potentisation, 90% alcohol is used (Verma and Vaid, 1997).

Certain substances that are insoluble, like calcium carbonate and graphites, are converted by a process known as trituration, in which they are continually ground until they become soluble. They are then diluted and used in the same way as naturally soluble substances. Substances that do not dissolve in a liquid vehicle may also be converted into liquid potencies (Verma and Vaid, 1997).

When making homoeopathic medication, a tincture is diluted in an alcohol or water mixture. This is done in one of two scales; the decimal scale (x) or the centesimal scale(c). In the decimal scale the dilution factor is 1:10, meaning that one part of the medication is used to nine parts of the solvent. In the centesimal scale the dilution factor is 1:100, meaning that one part medication is used to ninety nine parts solvent (Verma and Vaid, 1997).

2.9.6 Mother Tinctures Ø

It is a therapeutic active agent that is extracted in an alcohol-water mixture of varying percentages of alcohol, depending on the solubility, stability and extractability of the potential ingredients. This alcohol extract is called the mother tincture. It is a base for subsequent homoeopathic potentised medicines. A mother tincture is composed of active phytochemicals in plants, and complex organic entities in animals, and physiologically

active chemicals. The toxicity of a mother tincture should be studied before it is used (Varma and Yadav, 2001).

2.9.7 Frequency of dose

One of the main principles of prescribing homoeopathically is the 'minimum dose'. This entails giving only the required amount to initiate a healing response. This depends on the seriousness and urgency of the complaint (Dannheisser and Edwards, 1988).
For very serious, urgent complaints that have a sudden or intense onset, one dose may be given every 5-30 minutes. Dosing may be stopped on improvement or repeated as needed. For serious complaints that are less intense, one dose may be given every 1-2 hours. For less serious complaints that come on less vigorously and progress more gradually, one dose may be given every 4-8 hours, or 3-4 times a day (Dannheisser and Edwards, 1988). Sometimes patients can prove a remedy. Provings are normally done by individuals or small groups. The purpose is to gather symptoms of a remedy. A proving is not the same as a clinical trial, as a clinical trial is more directed towards physical symptoms (Vries, 2004). Patients can also be aggravated by certain remedies. This is a temporary intensification of symptoms. This can happen because symptoms move in the direction of cure. It can also occur if the prescribed potency of the remedy is higher than needed, repeated too often or taken too soon. Aggravations normally occur in chronic conditions (King, 2004).

The following remedy has symptoms with the symptom complex consistent with that associated with insomnia.

2.10 *Passiflora incarnata*

The common names for *Passiflora incarnata* Ø are; passion flower, passion vine and maypop. The plant is a climbing vine native to South America, but is now also grown in the USA and India. The dried leafy aerial parts, which normally include the flower and

fruit, are used pharmaceutically. The flower shows the distinctive shape of a cross, and gives the name passion (Heinrich *et al*, 2004).

Passiflora incarnata Ø is part of the granadilla family. The active ingredients are the alkaloids made up of harmine, harman, harmaline, harmalol and passaflorine and, flavonoids made up of apigenin and various glycosides, orientin, isovitexin and vitexen (Wren, 1998). The flavonoids in *Passiflora incarnata* are the primary constituents that are responsible for its relaxing and anti- anxiety effects. It also contains chemicals known as harmala alkaloids which are thought to block an enzyme involved in depression (Akhondzadeh *et al*, 2007).

The historical medicinal uses of *Passiflora incarnata Ø* include; the treatment of insomnia, hysteria, nervous tachycardia and neuralgia. Modern pharmaceutical uses include; nervous restlessness and insomnia due to nervous tension (Heinrich *et al*, 2004). *Passiflora incarnata* is available in several homoeopathic remedies and it comes as a liquid extract, tincture, crude extract and dried herb. This herb also has a tendency of making one feel relaxed (Fetrow and Avila, 2000). The medicinal use of *Passiflora incarnata Ø* is as a sedative, hypnotic and antispasmodic. The flavonoids in *Passiflora incarnata Ø* are the primary constituents responsible for its relaxing and anti anxiety effects (Wren, 1998). *Passiflora incarnata Ø* is used as a mild phytomedicine in chronic fatigue syndrome, nervousness and anxiety (Heinrich *et al*, 2004).It is very useful in all conditions resulting from impaired nerve functions and is invaluable in treating insomnia (Sinha, 1981).

Insomnia is associated with key symptoms like; the inability to fall asleep, frequent wakefulness at night and restlessness. *Passiflora incarnata Ø* acts as a sedative and a hypnotic, and it calms the nervous system to promote sleep (Ody, 1993). It is also thought to aid the transition into a restful sleep without the 'narcotic' hangover effect (Hoffmann, 1991). In the Homoeopathic Materia Medica, *Passiflora incarnata Ø* is said to have a calming effect on the nervous system. It has been clinically recommended for treating insomnia and producing normal sleep. It is used on individuals who are restless and

wakeful resulting from exhaustion, mental worries and over working (Vermeulen, 2002). Vermeulen (2001) suggests taking 30 and 60 drops of *Passiflora incarnata Ø* for a therapeutic effect.

Passiflora incarnata Ø is generally considered safe. It is found in many of the over the counter medications for insomnia. Allergic reactions such as hives or vasculitis have been known to occur in people working with *Passiflora incarnata Ø,* but this is extremely rare (Bilia *et al*, 2005). However there have been isolated reactions involving nausea and tachycardia in one case, and vasculitis in another (Heinrich *et al*, 2004).

In a study done on the sedative and hypnotic effects of *Kava kava* and *Passiflora incarnata Ø* extracts on mice, it was concluded that *Kava kava* and *Passiflora incarnata Ø* extracts, induced a significant prolongation of the sleep phase (Capasso and Sorrentino, 2005). There has not been much research done using *Passiflora incarnata Ø* as a single remedy, and this study aims to see how effective this remedy is in reducing insomnia.

2.10.1 Homoeopathic Treatment of Insomnia

A homoeopathic treatment would typically involve taking a complete case and matching a remedy to the totality of symptoms of the patient (Vithoulkas, 1980). There are other remedies, besides *Passiflora incarnata Ø,* which can be considered as an almost specific in the treatment of insomnia, such as; *Coffea cruda* and *Avena sativa* (Vermeulen, 2001).

Coffea cruda is also known as coffee. It is used for insomnia caused by mental activity, flow of ideas and nervous excitability. Patients may experience sleeplessness after pleasurable excitement (Vermeulen, 2001).

Avena sativa, most commonly known as oats, is used for both physical and nervous debility. It is also used as an antidepressant, a restorative nerve tonic (Ody, 1993). *Avena sativa* has a selective action on the brain and nervous system. It is used for sleeplessness especially in alcoholics (Vermeulen, 2001). In the homoeopathic Materia Medica, it is

recommended that *Avena sativa* is taken as a tincture, 10 -20 drops in warm water (Boericke, 2000).

2.10.2 Past Research on Insomnia

A previous homoeopathic study used *Avena sativa* Comp® in the treatment of insomnia. This study indicated that this remedy caused a statistically significant decrease in fatigue, caused evening sleepiness, and improved the subject's perception of the quality of their sleep (Roohani, 1998).

A homoeopathic research by Pellow 2002, using homoeopathic similimum treatments on 10 peri- or postmenopausal insomniacs helped decrease fatigue and sleepiness in varying degrees in each subject, and improved the subject's perception of the quality of their sleep.

CHAPTER THREE

METHODOLOGY

3.1 Study design

This study was a double blind placebo controlled study. The study took place over a period of 4 weeks. The treatment group was compared to the placebo control group, in order to evaluate the efficacy of *Passiflora incarnata* Ø, in the treatment of insomnia.

A total of 30 participants took part in the study, of which fifteen participants received the placebo medication, and fifteen received the homoeopathic medication.

3.2 Subject Selection

All participants between the ages of 19 and 49 were recruited by means of advertisements in local newspapers, e-mails and pamphlets that were distributed in and around the University of Johannesburg (Doornfontein), the health clinic, health shops, shopping malls, residential areas and the sleep unit at the University of Witwatersrand.

3.3 Inclusion and Exclusion Criteria

3.3.1 Inclusion Criteria

- Participants had to be suffering from insomnia for not more than 1 year.
- The insomnia experienced had to be associated with nervous excitability, which manifested as a difficulty in falling asleep.

3.3.2 Exclusion Criteria

- Participants taking prescribed medication for insomnia.
- Participants' taking over the counter medication for insomnia more than 3 times a week.
- Insomnia which is a result of side effects of treatment or disease process such as; obstructive sleep apnoea, restless leg syndrome, depression or narcolepsy. This was determined through an assessment questionnaire. If participants answered YES to questions 20, 22, 23, 24, 25, 26 and depressed to question 19, they did not qualify for the above study (Appendix B).
- Participants allergic to granadillas.
- Participants with chronic diseases or taking chronic medication.

3.4 Materials

3.4.1 Homoeopathic Intervention

The homoeopathic medication, *Passiflora incarnata* Ø, was prepared and purchased from Natura Homoeopathic Laboratory in Pretoria. *Passiflora incarnata* Ø was placed in 15x 50ml amber glass bottles and the placebo which was made of 20% diluted alcohol was also placed in 15 x 50ml amber glass bottles. The placebo bottles were identical to the medicated bottles.

3.4.2 Dispensing of the Medication

The medication was randomised by an independent pharmacist at Natura Homoeopathic Laboratories, whereby each bottle was numbered. All bottles were grouped in two's; either 2 placebos or 2 medicated bottles had an elastic band around it. Neither the researcher nor the participants were aware of which bottles contained the homoeopathic

medication and which contained the placebo. This information was only divulged to the researcher at the end of the study.

Each participant received 2 bottles of medication, to last them the duration of the study. Participants either received 2 bottles of the placebo or 2 bottles containing the medication.

3.5 Methodology

The steps followed by the researcher were as follows:

- After the participant responded to the advertisement an appointment was made and the participants were seen by the researcher at their convenience.
- After the researcher fully explained the study to the participant, a patient information consent form (Appendix A) was signed by the participant.
- A questionnaire (Appendix B) was completed by all prospective participants, in order to ascertain their eligibility for the study and to obtain data.
- The eligible participant's blood pressure, pulse rate, respiratory rate and temperature were then taken in order to monitor the patient.
- Participants were given 2 x 50ml bottles of medication, and they were instructed to complete the first bottle before starting the second.
- Participants were instructed to dilute fifty drops of the medication in 20ml of water twenty minutes before going to bed. They were requested to take medication in this way for the period of four weeks.
- Participants were given a sleep diary (Appendix C) and shown on the initial consultation how to complete it every morning. They filled in the sleep dairy based on the previous nights sleep.
- Participants were allowed to take over the counter medication if their insomnia was extreme, in which case they had to indicate what medication they took, and the day on which it had been taken, in the patient sleep diary given to them.
- An appointment was then made with the participant for a follow up visit in week two and week four.

- At each follow up visit the sleep diary (Appendix C) was checked to encourage compliance and a case history (Appendix D) was taken.
- The participant's blood pressure, pulse rate, respiratory rate and temperature were taken to monitor general well being.

3.6 Questionnaires and Observations

3.6.1 Patient Information and Consent Form (Appendix A)

The purpose of this form was to inform the patients about the following:

- Symptoms commonly experienced in insomnia.
- Reason why the research was to be conducted.
- The potential benefits to those who received the active medication.
- Participation in the study was voluntary and they were free to refuse to participate, or to withdraw their consent and discontinue participation at any time.
- Any questions would be answered at any time.

A signed copy of the consent form was made available to each participant.

3.6.2 Initial Questionnaire (Appendix B)

This questionnaire (Appendix B) was completed by all prospective participants, in order to ascertain their eligibility for the study. This questionnaire was also used to gather personal data such as, age and sex, history of insomnia, as well as information on lifestyle and habits.

3.6.3 Sleep Diary (Appendix C)

This diary was completed each day by the participant. It was used to monitor the participant's sleep each night.

3.6.4 Follow-up Form (Appendix D)

This form was completed by the researcher with the participant on the 2nd and the 4th week of the study. It was done to monitor any improvements in the patient's sleep and to encourage patient compliance.

3.7 Reliability and Validity Measures

Quality of data reliability was improved through a sleep diary (Appendix C), which is a standard procedure in insomnia studies. The sleep diary and the initial questionnaire, (Appendix B) were drawn up together with the statistician and the sleep unit at the Witwatersrand Medical School. The initial questionnaire was a modified version of the "Sleep Disorders Questionnaire" (Violani, 2004). This is a standard procedure at the sleep unit, to modify a sleep questionnaire and sleep diary to fit a specific study. Questions in the sleep diary measure parameters of the study. All participants were given the same sleep diary which was checked at week two and week four to encourage compliance. A standard case history (Appendix D) was also taken at each follow-up. All results were compared to the initial assessment and changes were recorded.

3.8 Ethical Consideration

This study was approved and passed by the Higher Degrees Committee on the 18 August 2006. The ethical clearance number is 44/06. This study was fully explained to the participant. The participant was requested to sign a consent form prior to the study. Participants were informed that their participation in the study was voluntary, and they were free to withdraw their consent at any stage. They were informed that they had the right to ask questions pertaining to the study. Participants were also informed about the above study, its significant benefit being an improvement of sleep. All information pertaining to participants was kept strictly confidential, and only the researcher had access to it. There were no anticipated risks in the above study.

3.9 Data Collection and Analysis

Once the clinical trial was completed, arrangement was made with the participant to collect the sleep diary at their convenience. The data was statistically analysed using the General Linear Model: Repeated Measures, Mann-Whitney test (non-parametric test), Cross Tabulation, Fisher's exact test and Regression analysis. The experimental group in the data analysis is known as the *Passiflora* group, and the control group is known as the placebo group (Crawford, 2007).

CHAPTER FOUR

RESULTS

4.1 Introduction to results

All results from this study were analysed using the General Linear Model statistical test. A P-value of less than P= 0.05 was considered significant, and greater than P= 0.05 is considered not significant. Passiflora was the group that received the medication, *Passiflora incarnata* Ø, and placebo was the group that received the placebo.

4.2 Analysis according to Demographics

There were 30 participants that took part in this study. None of the participants dropped out of the study.

4.2.1 Age

Participants between the ages of 19 and 49 were recruited for the study.

Table 4.1. Illustrates Age Frequency.

The following table illustrates the different age groups of participants that took part in the study. However 1 participant did not fill in their age on the initial questionnaire, but they did fall within the range.

	Frequency	Percent	Valid Percent	Cumulative Percent		
Valid	19	1	3.3	3.4	3.4
	21	2	6.7	6.9	10.3
	22	1	3.3	3.4	13.8

	24	3	10.0	10.3	24.1
	25	1	3.3	3.4	27.6
	26	3	10.0	10.3	37.9
	27	3	10.0	10.3	48.3
	28	1	3.3	3.4	51.7
	29	1	3.3	3.4	55.2
	31	1	3.3	3.4	58.6
	32	1	3.3	3.4	62.1
	33	1	3.3	3.4	65.5
	34	1	3.3	3.4	69.0
	35	1	3.3	3.4	72.4
	39	1	3.3	3.4	75.9
	40	2	6.7	6.9	82.8
	46	3	10.0	10.3	93.1
	49	2	6.7	6.9	100.0
	Total	29	96.7	100.0	
Missing	**System**	1	3.3		
Total		30	100.0		

N= 29

Std. Dev. =9.089

Mean= 31.59

The highest frequency of participants fell between the ages of 24 and 49. The mean age of all 29 participants was 31 and 32 years.

4.2.2 Age frequency in Passiflora and placebo groups

Table 4.2 Illustrates age frequency in the Passiflora and placebo groups.

The following table illustrates the age frequency divided into the 2 groups, 1 being Passiflora and the other the placebo group. It should be noted that 1 participant in the Passiflora group did not complete their age on the initial questionnaire, but they did fall within the age frequency.

Age (years)						
Group			**Frequency**	**Percent**	**Valid Percent**	**Cumulative Percent**
Passiflora	**Valid**	**19**	1	6.7	7.1	7.1
		21	2	13.3	14.3	21.4
		25	1	6.7	7.1	28.6
		26	1	6.7	7.1	35.7
		27	3	20.0	21.4	57.1
		32	1	6.7	7.1	64.3
		33	1	6.7	7.1	71.4
		35	1	6.7	7.1	78.6
		39	1	6.7	7.1	85.7
		40	2	13.3	14.3	100.0
		Total	14	93.3	100.0	
	Missing	**System**	1	6.7		
	Total		15	100.0		
Placebo	**Valid**	**22**	1	6.7	6.7	6.7
		24	3	20.0	20.0	26.7
		26	2	13.3	13.3	40.0
		28	1	6.7	6.7	46.7
		29	1	6.7	6.7	53.3
		31	1	6.7	6.7	60.0
		34	1	6.7	6.7	66.7
		46	3	20.0	20.0	86.7
		49	2	13.3	13.3	100.0
		Total	15	100.0	100.0	

In the Passiflora group the age frequency was between the ages of 19 and 40. In the placebo group the age frequency was between the ages of 22 and 49.

4.2.3 Gender frequency

Table 4.3. Illustrates the percentage distribution of treatment among male and female.

The following table shows the distribution of males and females in both groups. It was by coincidence that 7 males and 8 females were part of both the Passiflora and placebo groups.

Gender

Group			Frequency	Percent	Valid Percent	Cumulative Percent
Passiflora	Valid	Male	7	46.7	46.7	46.7
		Female	8	53.3	53.3	100.0
		Total	15	100.0	100.0	
Placebo	Valid	Male	7	46.7	46.7	46.7
		Female	8	53.3	53.3	100.0
		Total	15	100.0	100.0	

46.7% of participants who received the homoeopathic medication, Passiflora, were male and 53.3% were female. The placebo group had the same percentages.

4.2.4 Marital status

Table 4.4 Illustrates the marital status of the participants distributed in the Passiflora group and placebo group.

The following table indicates the marital status of participants who took part in the study distributed into the 2 groups. One participant in the Passiflora group did not complete the marital status part of the questionnaire.

Marital Status

Group			Frequency	Percent	Valid Percent	Cumulative Percent
Passiflora	Valid	Single	6	40.0	42.9	42.9

		Married	6	40.0	42.9	85.7
		Divorced	1	6.7	7.1	92.9
		Widowed	1	6.7	7.1	100.0
		Total	14	93.3	100.0	
	Missing	System	1	6.7		
	Total		15	100.0		
Placebo	Valid	Single	5	33.3	33.3	33.3
		Married	8	53.3	53.3	86.7
		Widowed	2	13.3	13.3	100.0
		Total	15	100.0	100.0	

In the Passiflora group 40% were single, 40% were married, 6.7 % were divorced and 6.7% were widowed. In the placebo group 33.3% were single, 53.3% were married and 13.3% were widowed.

4.3 Data obtained from initial questionnaire

All results obtained from this questionnaire, were used to determine the type of insomnia that participants were suffering from, and the duration of their insomnia. All information obtained from this questionnaire was prior to participants beginning the study.

4.3.1 Type of thoughts before going to bed

Table 4.5 Illustrates types of thoughts participants had, distributed in the Passiflora group and placebo group.

The following table was completed by participants on the first consultation. It illustrates the kind of thoughts participants had when trying to fall asleep.

What kinds of thoughts go through your mind when trying to sleep?						
Group			Frequency	Percent	Valid Percent	Cumulative Percent
Passiflora	Valid	Pleasant thoughts	1	6.7	6.7	6.7
		Stressful thoughts	10	66.7	66.7	73.3
		Worries	4	26.7	26.7	100.0
		Total	15	100.0	100.0	
Placebo	Valid	Stressful thoughts	12	80.0	80.0	80.0
		Worries	3	20.0	20.0	100.0
		Total	15	100.0	100.0	

66.7% of participants in the Passiflora group had stressful thoughts, 6.7% had pleasant thoughts, and 26.7% were worried before going to bed. In the placebo group 80% of participants had stressful thoughts and 20% were worried.

4.3.2 Sleep arrangement

Table 4.6 Illustrates sleeping arrangement of participants distributed in the Passiflora group and the placebo group.

The following table illustrates how participants slept every night.

How do you sleep?						
Group			Frequency	Percent	Valid Percent	Cumulative Percent
Passiflora	Valid	Double bed with partner	7	46.7	46.7	46.7
		Alone	8	53.3	53.3	100.0
		Total	15	100.0	100.0	
Placebo	Valid	Double bed with partner	8	53.3	53.3	53.3
		Single bed in same room with partner	2	13.3	13.3	66.7
		Alone	5	33.3	33.3	100.0
		Total	15	100.0	100.0	

In the Passiflora group 46.7% of participants slept with a partner, and 53.3% slept alone. In the placebo group 53.3% slept with a partner, 13.3% slept on a single bed with a partner in the room and 33.3% slept alone.

4.3.3 Number of hours slept initially

Table 4.7 Illustrates the minimum hours slept.

How many hours do you sleep per night? – Min

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	2.0	2	6.7	7.4	7.4
	3.0	3	10.0	11.1	18.5
	4.0	14	46.7	51.9	70.4
	5.0	6	20.0	22.2	92.6
	6.0	2	6.7	7.4	100.0
	Total	27	90.0	100.0	
Missing	System	3	10.0		
Total		30	100.0		

46.7% of the participants got 4 hours sleep, 20% got 5 hours sleep, 10% got 3 hours sleep, 6.7% got 6 hours sleep, and 6.7% of participants got 2 hours sleep. Of 30 participants 3 did not complete their minimum hours of sleep they got prior to the study.

Table 4.8 Illustrates the maximum hours slept.

How many hours do you sleep per night? – Max

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	4.0	2	6.7	6.7	6.7
	5.0	13	43.3	43.3	50.0
	6.0	8	26.7	26.7	76.7
	7.0	5	16.7	16.7	93.3
	8.0	2	6.7	6.7	100.0

	Total	30	100.0	100.0	

43.3% of participants got 5 hours sleep, 26.7% got 6 hours sleep, 16.7% got 7 hours sleep, 6.7% got 8 hours sleep and 6.7% got 4 hours sleep.

4.4 Data obtained from sleep diary

All results were obtained from the sleep diary to determine the amount of participants who had an improvement in their quality of sleep. The quality of sleep was assessed in terms of duration of sleep, the degree of feeling refreshed upon waking and satisfaction with sleep.

4.4.1 Number of hours slept split by gender

The graphs below, Figure 4.1a and 4.1b, illustrate the average number of hours slept by the participants split by gender, which includes both the placebo and Passiflora groups, during the 4 weeks of the study. In Figure 4.1a, the group is divided into male and female and into the 4 weeks of the study. The graph shows on an average, which gender had more sleep per week and overall which gender slept more. The overall P- value for the specified time was P= 0,125. This was statistically not significant.

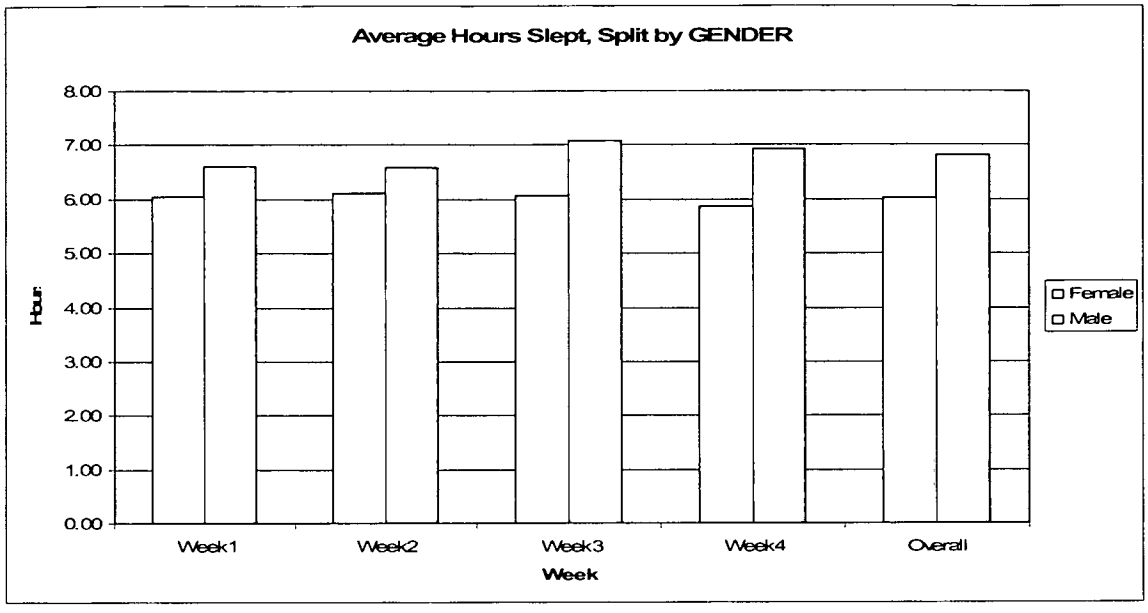

Figure 4.1a Graph depicting the average hours slept split by gender.

Figure 4.1b, is a more concise graph, although it does contain the same information as the graph above, it separates the males from the females. This shows that over the 4 week period the males had more of an improvement in the number of hours slept.

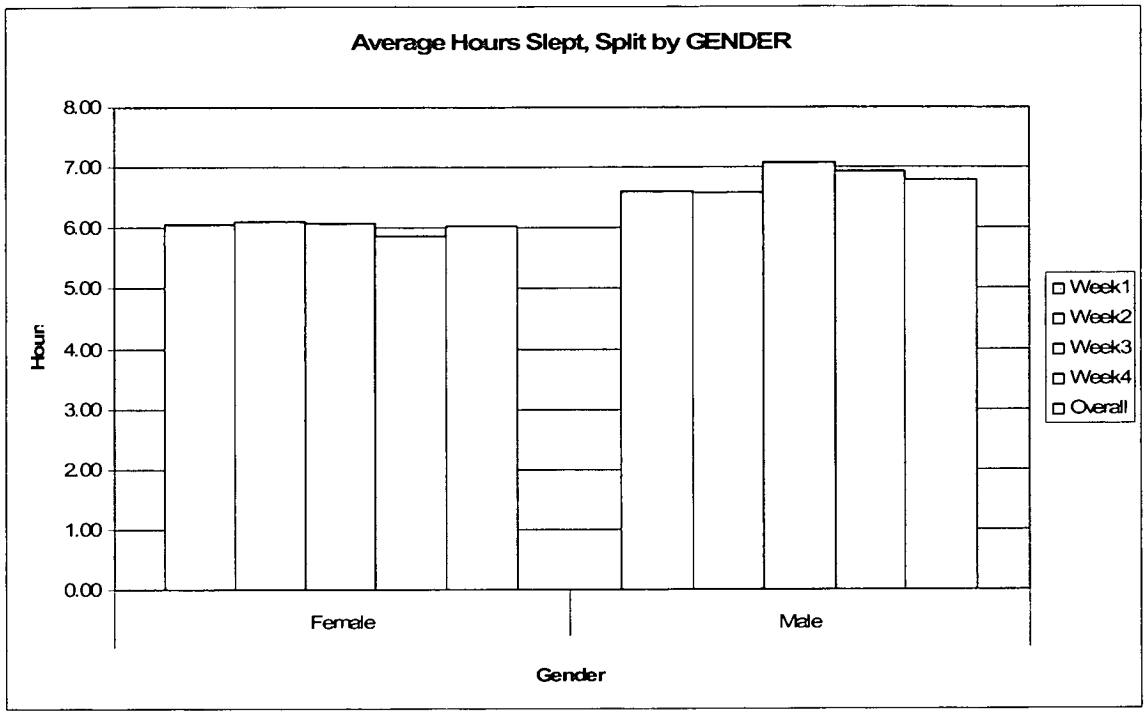

Figure 4.1b Graph depicting the average hours slept split by gender.

4.4.2 Number of hours slept split by group – Passiflora and Placebo

In Figure 4.2a and 4.2b, the participants are split into the Passiflora and placebo groups. The numbers of hours slept by both groups are depicted in the following graphs. In Figure 4.2a, the average hours slept can be seen from week 1 to week 4. This shows that the placebo group slept more on a week to week basis. The overall P- value for the specified time was P= 0,449. This is statistically not significant.

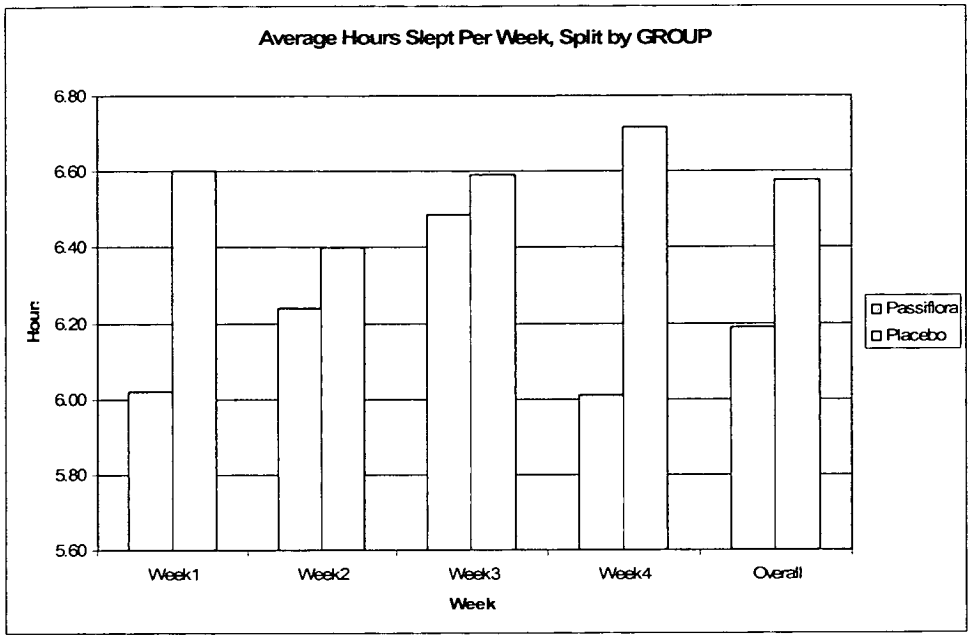

Figure 4.2a Graph depicting average hours slept split by Passiflora and placebo groups

Figure 4.2b, illustrates the same information as the graph above, but it puts the Passiflora and placebo groups on opposite ends of the graph. In this way one can see that the placebo group had an improvement in the number of hours slept especially in week 4 compared to that of the Passiflora group.

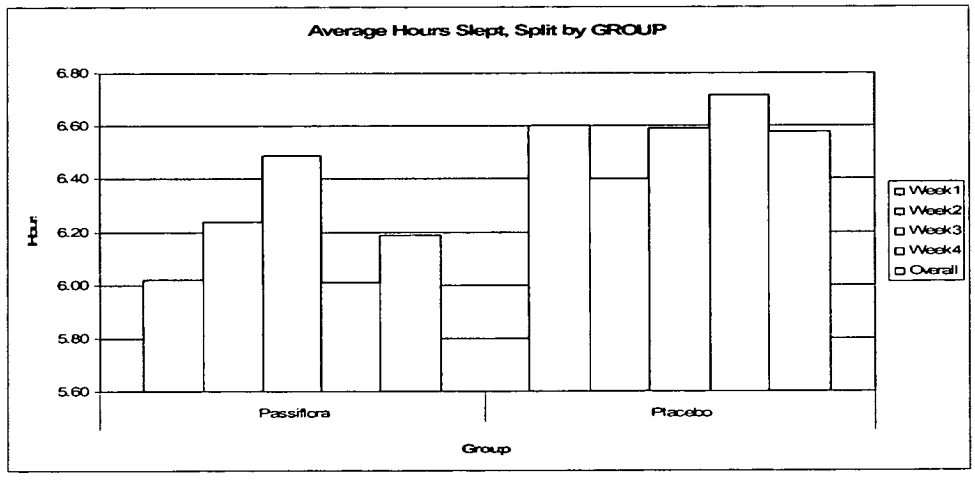

Figure 4.2b Graph depicting average hours slept split by Passiflora and placebo groups.

4.4.3 Average number of hours split by group and gender

The following graphs, Figure 4.3a and 4.3b, give the average number of hours slept split by both group and gender. Figure 4.3a illustrates the 4 weeks of the study and divides each week into the 2 gender, male and female, and the 2 groups, Passiflora and placebo groups, depicting the average number of hours slept. The overall P- value for the specified time was P= 0,244. This was statistically not significant.

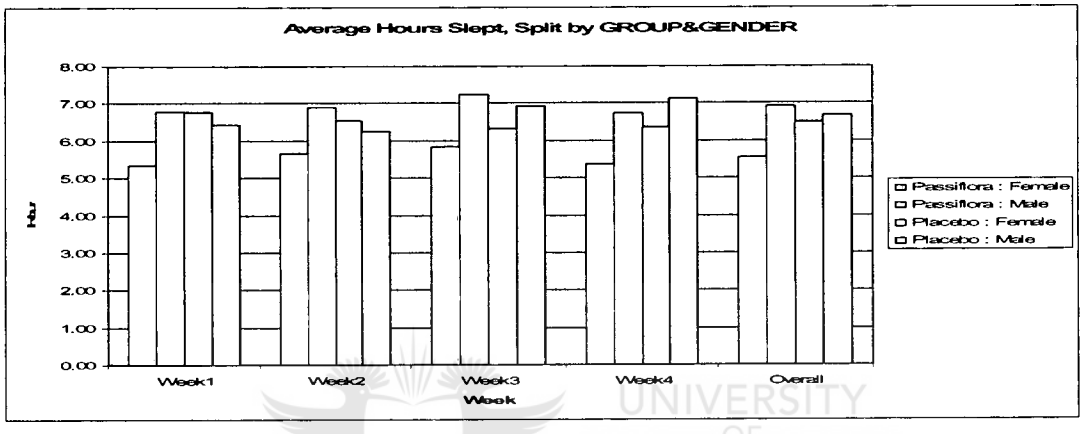

Figure 4.3a Average hours split by group and gender.

Figure 4.3b, takes the Passiflora male, Passiflora female, placebo male and placebo female and groups them over the 4 week period. In this way one can see that the Passiflora males had an overall improvement in the average number of hours slept.

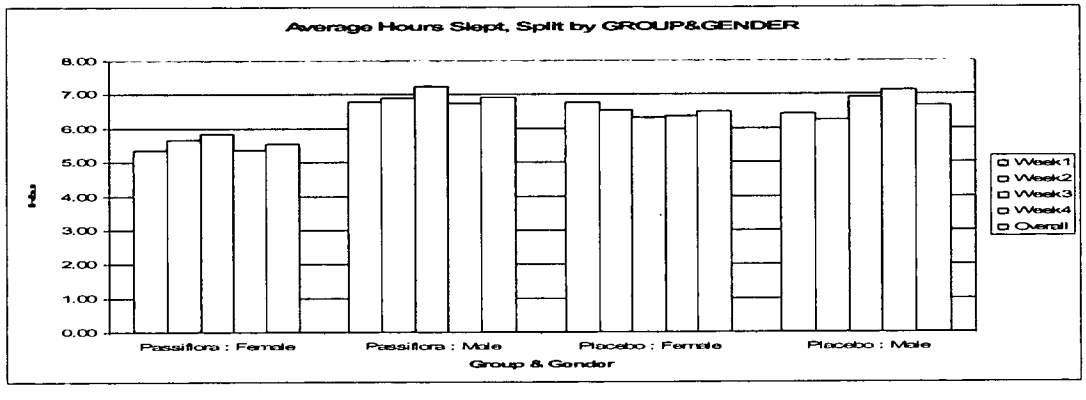

Figure 4.3b Average hours split by group and gender.

4.4.4 Difference in average sleep

The following graph, Figure 4.4, gives us the average sleep that the participants experienced over the entire period of the study. There were 30 participants in the study. The yellow bars represent participants taking the medication, *Passiflora incarnata* Ø, and the black bars indicate participants taking the placebo. This graph takes the average number of hours each participant slept initially, before the study, and subtracted that from the average number of hours each participant slept once completing the study. Participants ranged from sleeping less after the study, to having no improvement, to sleeping better after the study.

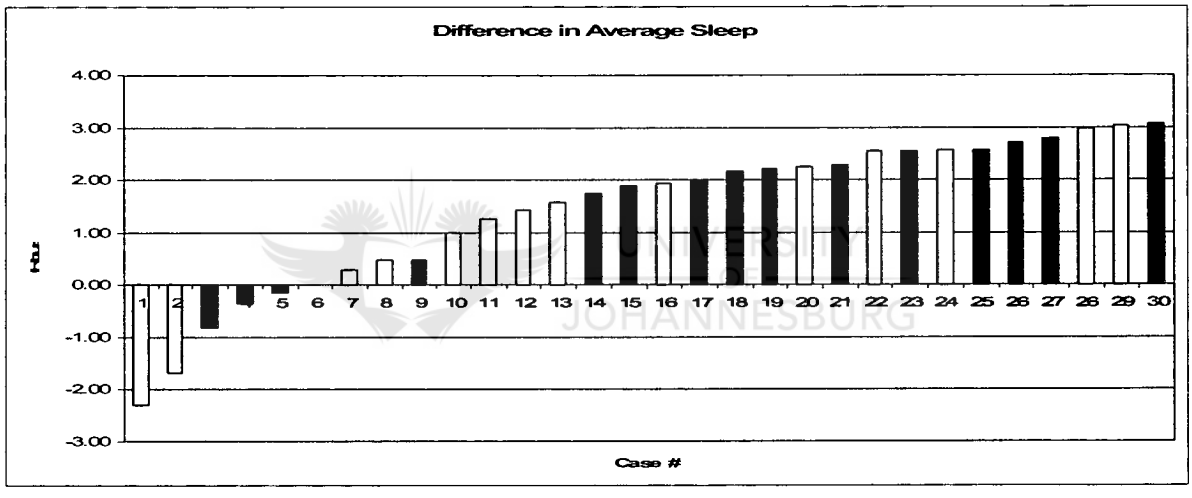

Figure 4.4 Graph depicting the difference in average sleep.

4.4.5 Average hours slept per case in the Passiflora group

Figure 4.5, illustrates the average number of hours slept by each participant, over the 4 weeks that the study took place. The participants represented in this graph were on the medication, *Passiflora incarnata* Ø.

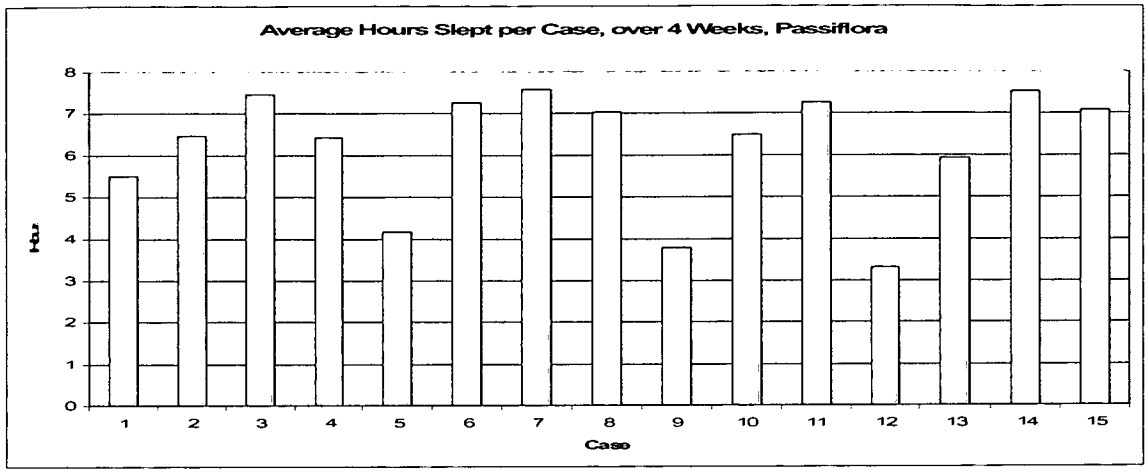

Figure 4.5 Average hours slept per case in the Passiflora group.

4.4.6 Average hours slept per case in the placebo group

The following graph, Figure 4.6, illustrates the average number of hours slept by each participant over the 4 weeks that the study took place. The participants represented in this graph were on the placebo.

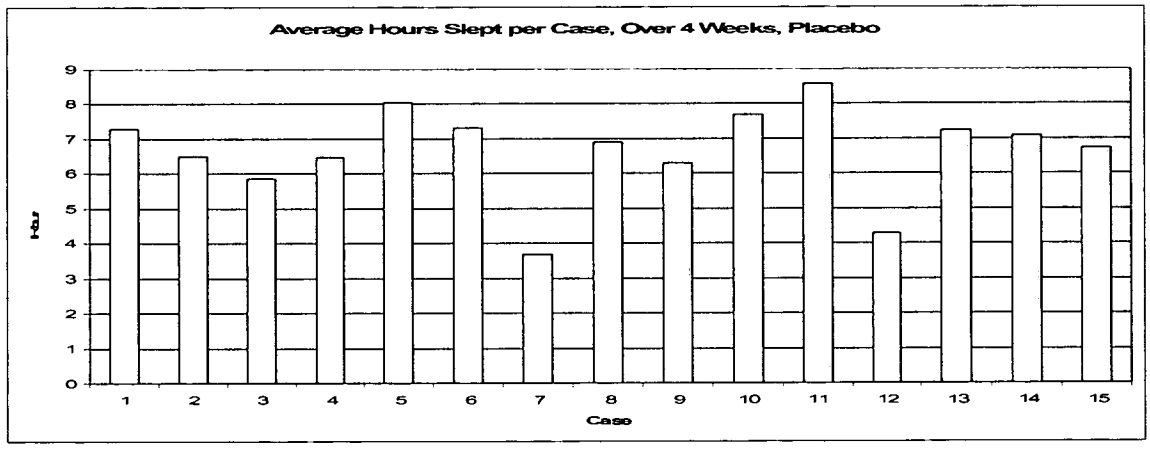

Figure 4.6 Average hours slept per case in the placebo group.

4.4.7 Average satisfaction with sleep split by Passiflora and placebo group

The following 2 graphs, Figure 4.7a and Figure 4.7b illustrates the average satisfaction with sleep, split by the Passiflora and placebo groups, during the study. The graphs depict the perception, participants had regarding their sleep and how satisfied thy felt with the previous nights sleep. Participants had to indicate whether they had a difficulty waking up- rating 1, unrefreshed – rating 2, tired- rating 3, alert- rating 4, or alert and refreshed- rating 5. The overall P- value for the specified time was P= 0,535. This was statistically not significant.

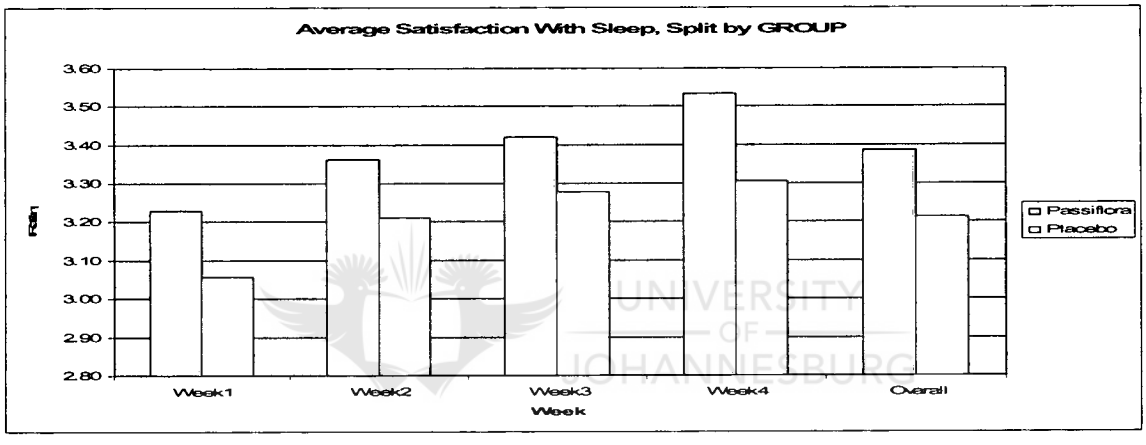

Figure 4.7a Graph depicting average satisfaction of sleep split by Passiflora and placebo groups.

The graph below depicts the average satisfaction with sleep, divided into the 2 groups, Passiflora and placebo. Both groups are on either end of the graph, and it is shown on a week to week basis, their perception with their sleep satisfaction.

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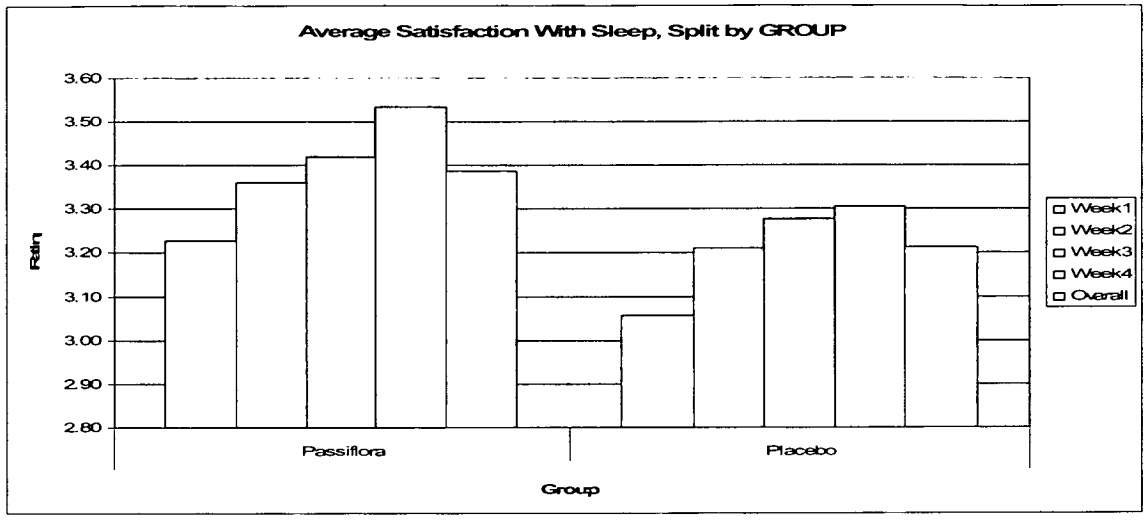

Figure 4.7b Graph depicting the average sleep satisfaction split by Passiflora and placebo.

4.4.8 Average satisfaction with sleep split by group and gender

Figure 4.8 represents average satisfaction with sleep, but in this graph it is further split into male and female. A graph like this gives one a better understanding of which gender, either the Passiflora group or the placebo group, had more satisfaction with their sleep. The overall P- value for the specified time was P= 0,046. This is statistically significant.

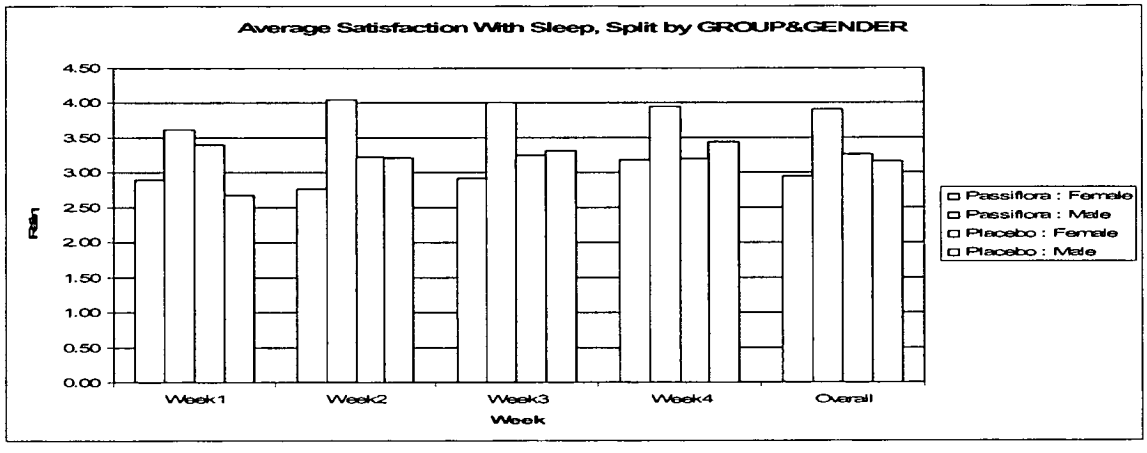

Figure 4.8 Graph depicting the average satisfaction with sleep split by group and gender.

4.4.9 Average satisfaction with sleep in the Passiflora group

Figure 4.9, illustrates the average satisfaction with sleep per case over the 4 weeks of the study. The graph below, takes each individual case in the Passiflora group, and works out their average satisfaction over the 4 weeks, based on the rating scale in the sleep diary.

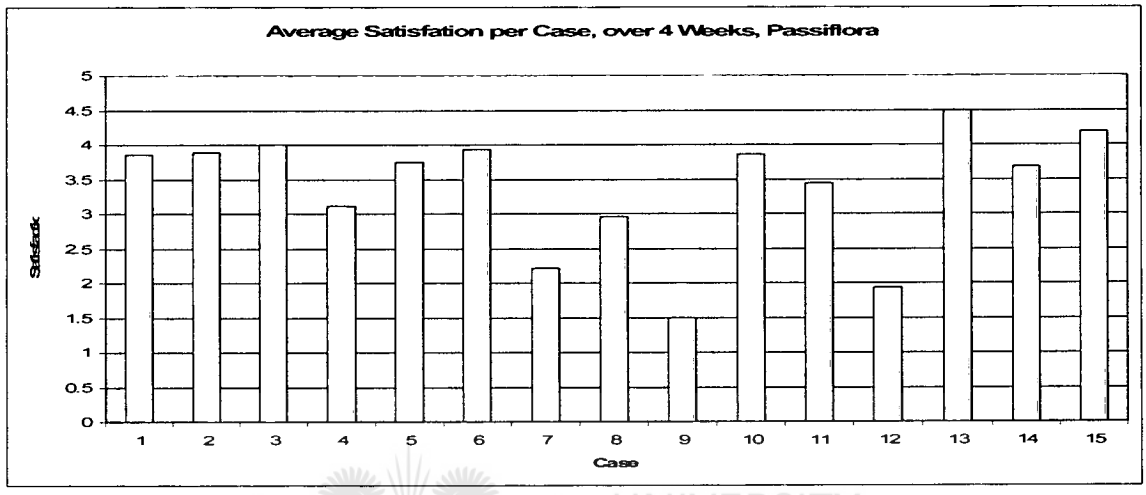

Figure 4.9 Average satisfaction with sleep per case over 4 weeks in the Passiflora group.

4.4.10 Average satisfaction with sleep in the placebo group

Figure 4.10, illustrates the average satisfaction with sleep per case in the placebo group over the 4 weeks of study. The graph below represents each of the 15 participants that made up the placebo group. Their overall average satisfaction with sleep can be seen below, based on the rating scale in the sleep diary.

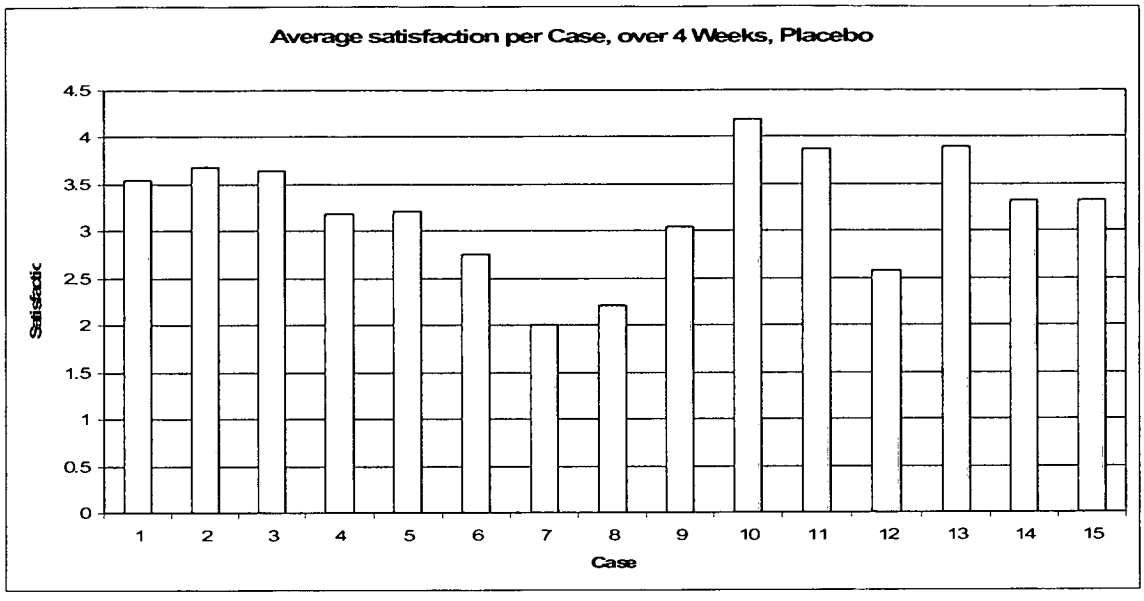

Figure 4.10 Average satisfaction with sleep per case over 4 weeks in the placebo group.

4.4.11 Average number of participants that noticed a change in their sleeping pattern split by gender

The following graph, Figure 4.11 illustrates the average number of participants that noticed a change in their sleeping patterns. The change that the participant was told to record was any improvement in their sleep, either they slept longer, or they felt more refreshed upon waking etc. The graph below shows one on a weekly basis, how many males and females noticed a change in their sleeping pattern. The P- values for number of participants that noticed a change in their sleeping pattern was given weekly. Week 1- P= 0,436; Week 2- P= 0,625; Week 3- P= 0,920; Week 4- P= 0,432. They were all statistically not significant.

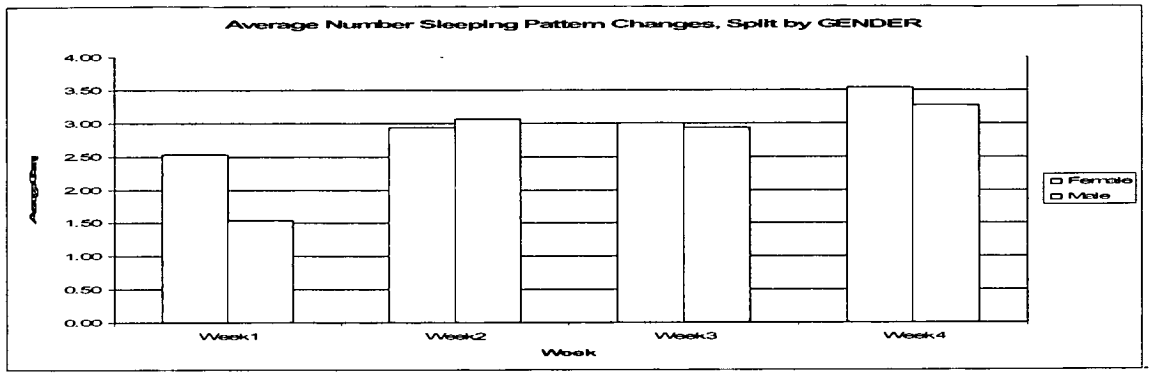

Figure 4.11 Graph depicting average number of sleeping pattern changes.

4.4.12 Average number of participants that noticed a change in their sleeping pattern split by Passiflora and placebo groups

The following graph, Figure 4.12 split in their groups, Passiflora and placebo, noticed a change in their sleeping pattern. Over the 4 weeks of the study, it was recorded on average how many participants on a weekly basis noticed a change in their sleep pattern. From the graph below, one is able to distinguish whether more participants that noticed a change either fell in the Passiflora or placebo group. The P- values for Week 1- P= 0,922; Week 2- P= 0,285; Week 3- P= 0,621; Week 4- P= 0,255. They were all statistically not significant.

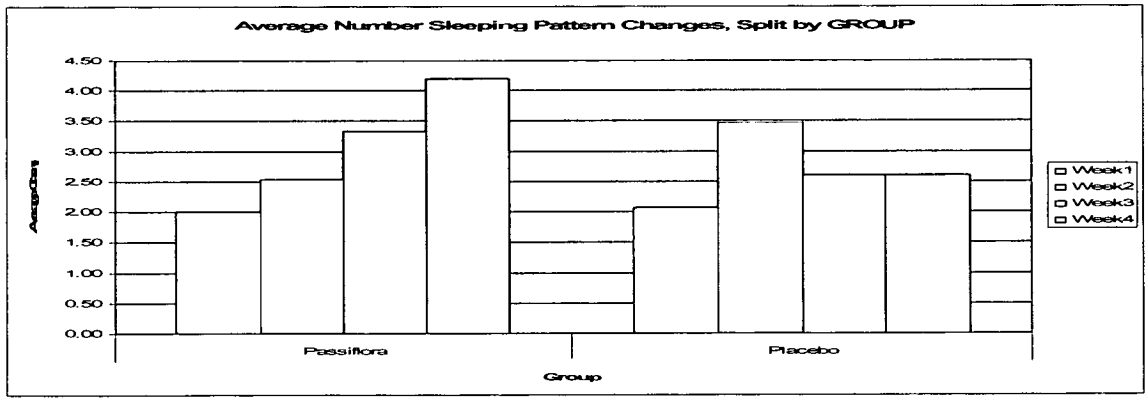

Figure 4.12 Graph depicting the number of participants that noticed a change in their sleeping patterns.

4.4.13 Average number of sleeping pattern changes split by group and gender

Figure 4.13, illustrates the number of participants divided in group and gender that noticed a change in their sleeping pattern. The graph below, takes the information from the above 2 graphs and puts it together. In this way one can see, on a week to week basis, which group, either Passiflora male or female, or placebo male or female noticed more changes in their sleeping pattern. The P- values for Week 1- P= 0,873; Week 2- P= 0,233; Week 3- P= 0,436; Week 4- P= 0,550. They were all statistically not significant.

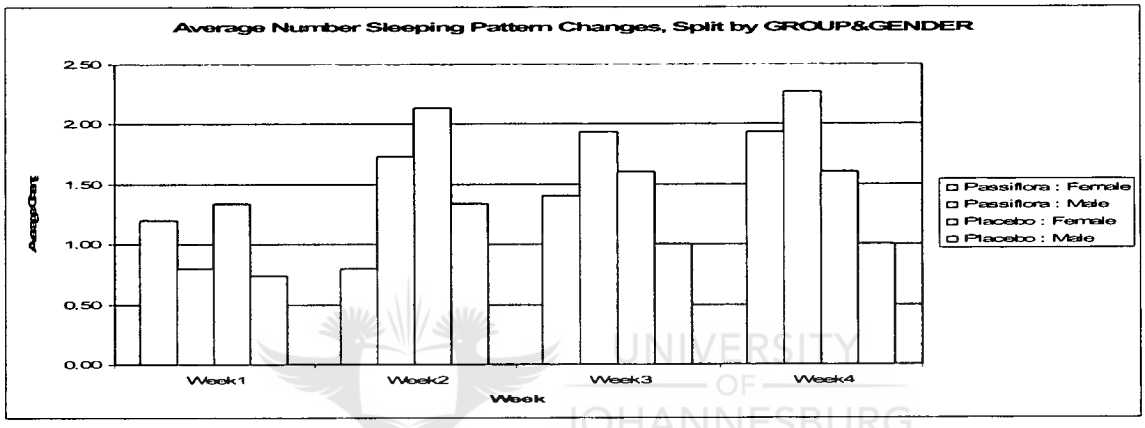

Figure 4.13 Average number of sleeping pattern changes split by group and gender.

4.4.14 Number of participants who noticed a change in their sleeping pattern every night during the study

Figure 4.14, illustrates how many participants noticed a change in their sleeping pattern, each night during the study, either from the Passiflora or placebo group. The following graph represents the 28 days that the study took place. The blue bar represents the Passiflora group and the red bar represents the placebo group. On each day, the graph shows how many participants, in either group, noticed a change in their sleeping pattern.

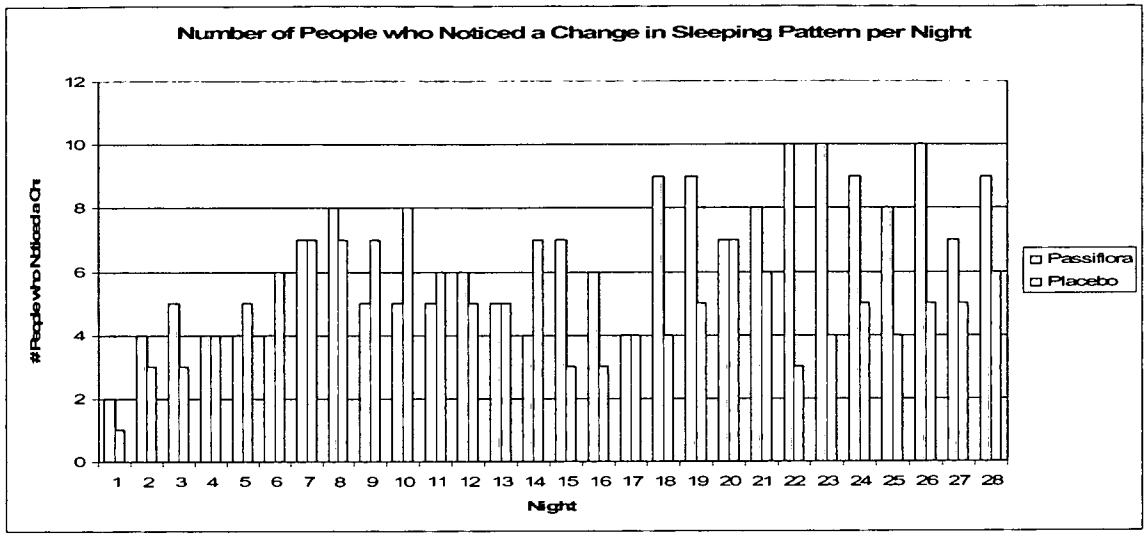

Figure 4.14 Number of participants that noticed a change in their sleep pattern.

CHAPTER FIVE

DISCUSSION

5.1 Age

The participants' age groups were determined according to frequency. The majority of participants in both groups were between the ages of 24 and 49.

5.2 Age frequency in the Passiflora and placebo groups

The researcher recruited participants between the ages of 18 and 50. Participants that took part in the study fell between the ages of 19 and 49. The majority of the participants in the Passiflora group were between the ages of 19 and 40, whereas in the placebo group the majority of the participants were between the ages of 22 and 49. Participants in both groups fell between similar age ranges and did not suffer from chronic insomnia but rather acute insomnia as they had it for less than a year. Acute insomnia could be a result of a change in environment, emotional crisis, a new baby, illness, or bereavement (Walsh *et al*, 1999; Nichols *et al*, 2007). Other studies could look at treating chronic insomnia using the remedy *Passiflora incarnata* Ø.

5.3 Gender frequency

There were 30 participants that took part in the study. More females than males were recruited. Of the 30 participants 53% were females and 46% were males. They were randomly, and equally, divided into 2 groups of 15 participants respectively. As stated in the literature review, insomnia is more common in females (Walsh *et al*, 1999).

5.4 Marital status and sleep arrangement

Of the 30 participants, 36.7% were single, 46.7% were married, 3.3% were divorced and 10% were widowed. Although there are no statistics on the effect of marital status on insomnia, the highest frequency of insomnia in this study occurred with the married participants. Within the Passiflora and the placebo group, the highest frequency of participants that suffered from insomnia were either married or single. Insomnia could be more common in married couples because of the other partner snoring, or because of stress within the marriage. In the case of single individuals, insomnia could be due to the stresses of being alone. In this study, with regards to sleep arrangement majority of participants that suffered from insomnia either slept with a partner or slept alone.

5.5 Type of thoughts before going to bed

The type of thoughts an individual has before going to bed, could affect the quality of sleep. When participants were asked to describe their thoughts before going to bed, in their initial questionnaire (Appendix A), 66.7% of participants in the Passiflora group had stressful thoughts, 6.7% had pleasant thoughts, and 26.7% were worried before going to bed. In the placebo group 80% of participants had stressful thoughts and 20% were worried. Kryger (2000) suggests that being relaxed prior to going to bed, reducing stressful factors in the bedroom and keeping the bedroom for sleeping only is more conducive to sleep hygiene.

5.6 Data obtained from sleep diary

The parameters measured in this study were the duration of sleep, satisfaction with sleep, and improved changes in sleeping patterns. Data obtained from the sleep diary is discussed under the following headings.

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5.6 Data obtained from sleep diary

The parameters measured in this study were the duration of sleep, satisfaction with sleep, and improved changes in sleeping patterns. Data obtained from the sleep diary is discussed under the following headings.

5.6.1 Duration of sleep

Although not statistically significant, P= 0,125 when split by gender, females had a trend of sleeping consistently less than males (Fig 4.1a and 4.1b), with males sleeping an overall average of about 1 hour more than females. There was also no pattern emerging in the sleeping times, they neither increased nor decreased but seem to ebb and flow.

With regards to the number of hours slept in the Passiflora and placebo groups, there was no statistical significance, P= 0,449 however the graph does show a surprising trend. The placebo group had a trend of sleeping longer than the Passiflora group. This was more evident in week 4 as the placebo group slept more than any other week. Although in the first 3 weeks the Passiflora group does show an improvement in the number of hours slept, a break is seen in week 4, as participants start sleeping less. The reasons for this are unknown. Possible explanations could be due to the short term effectiveness of the medication, a possible lack of consistency in participants in taking the medication as indicated, or that the *Passiflora incarnata* Ø was causing an aggravation in some participants causing an intensification of their symptoms (King, 2004).

The groups were further divided into Passiflora male, Passiflora female, placebo male and placebo female. Although not statistically significant, P= 0,244 the males in the Passiflora group had a trend of a higher average in the number of hours slept over the 4 weeks. This shows that the medication may act differently in the genders.

A difference in average sleep of each individual participant was obtained by taking the average amount of sleep that each participant had before the study, and comparing it to the average amount of sleep that the participant had during the study. Once this was done it was determined which participants had an improvement in the duration of their sleep, and which participants did not have any improvement. In the Passiflora group, participant 1 slept 2 hours less than before the trial. A possible explanation could be that the participant was experiencing an aggravation or was proving the remedy. A proving of a remedy is not the same as a clinical trial. A proving is the symptoms produced by the

action of the remedy and is used to understand the remedy range of action. From a proving it can be ascertained what that particular remedy could be used for (Vries, 2004). An aggravation is a temporary intensification of the patient's symptoms (King, 2004). Throughout the clinical trial there were 2 participants that did not have any improvement in their sleep (Figure 4.4). Apart from these 2 participants both groups were similar in the difference in average sleep.

5.6.2 Satisfaction with sleep

Although not statistically significant, P= 0,535 the Passiflora group slightly out performed the placebo group with regards to satisfaction with sleep. The Passiflora group went from being tired to more alert, and the placebo group had a trend of not feeling refreshed to feeling more tired.

Of the 15 participants in the *Passiflora* group, 46% were feeling more alert and 13% were feeling alert and refreshed, 33% were feeling tired and not refreshed and 6% had a difficulty waking up.

In the placebo group, 33% of the participants felt more alert, 26% felt alert and refreshed and 40% felt tired and not refreshed.

The Passiflora and placebo group was further divided into Passiflora male, Passiflora female, placebo male and placebo female. The Passiflora males were significantly, (P= 0,046) more satisfied with their sleep as compared to the other groups.

5.6.3 Improved changes in sleeping pattern

Although not statistically significant, the Passiflora group shows a steady upward trend of an improved change in their sleeping pattern. With regards to the placebo group a difference is noted in Week 4 but it is not statistically significant.

When further divided into Passiflora male, Passiflora female, placebo male and placebo female, the Passiflora males shows a steady trend of an improved change in their sleeping pattern as compared to other groups but this is not statistically significant.

Over the 4 week cycle, both the Passiflora and placebo groups showed an ebb and flow cycle in their sleeping patterns, of occasional improvement followed by episodes of less improvement or deterioration. It is noted that while the placebo group stayed within the cycle range, the Passiflora group shows an upward trend of improvement (Fig 4.14).

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

This study was subjective, as participants recorded their symptoms according to their experience of them. The male participants in the Passiflora group showed more of a trend of improvement than the female participants in their sleeping pattern as well as satisfaction with their sleep. Over the 4 weeks, they had a consistently higher average in the number of hours slept. Although the males in the Passiflora group did show an improvement it was not statistically significant overall.

With regards to the study, the following trends could be observed. Overall males showed an improvement in the number of hours slept compared to females and females noticed more of a change in their sleeping pattern as compared to males.

The placebo group slept more overall than the Passiflora group. The Passiflora group slightly out performed the placebo group with regards to satisfaction with their sleep. More participants in the Passiflora group noticed a change in their sleeping pattern as compared to the placebo group.

The Passiflora males had a higher average in the number of hours slept over the 4 weeks of the study. The Passiflora males were also more satisfied with their sleep than the Passiflora females and the placebo males and females. This was statistically significant. The Passiflora males showed a steady increase in the amount of participants that noticed an improvement in their sleeping pattern.

From the above information one can conclude that more research needs to be done regarding the effect of *Passiflora incarnata* Ø on males in insomnia.

There was no statistical difference between the Passiflora group and the placebo group in terms of the parameters being measured. Therefore the null hypothesis cannot be rejected. The only significant finding was that Passiflora males were more satisfied with their sleep as compared to the Passiflora female. Sleep satisfaction is an important factor in the mitigation of insomnia.

No side effects or adverse reactions were reported by the participants taking *Passiflora incarnata Ø*.

6.2 Recommendations

A comparative study is recommended to confirm that the remedy *Passiflora incarnata Ø* is more effective in males than in females.

It is recommended that further studies be conducted on a larger sample size. Follow up studies should be conducted at 6 to 12 month intervals, to determine the effect of *Passiflora incarnata Ø*, in the long term treatment of insomnia.

It is also recommended that a study be done, initially administering the placebo to all participants for a 2 week period, and thereafter administering the homoeopathic medication for a 2 week period. The results from the placebo trial should be compared to that of the homoeopathic trial.

It is also suggested that experimenting with different potencies and dosages may prove to be of benefit to patients suffering from insomnia.

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APPENDICES:

Appendix A

A collaborative study to determine the effects of *Passiflora incarnata* Ø on insomnia

Dear participant

I invite you to participate in a study conducted by myself Sunaina Amiraj-Surujparsad for a Master degree in Homoeopathy. The purpose of the study is to determine the effect of *Passiflora incarnata* on insomnia. .

Passiflora incarnata is a homoeopathic remedy used to calm a person and help them fall asleep. It is very safe and is found in many of the over the counter medications used for insomnia.

As a participant in this study you should be suffering from insomnia, which is a difficulty in falling asleep. You should not have been suffering from insomnia for more than a year and should not be on any form of treatment for your insomnia.

There are two groups and you may fall into anyone of them. One of the groups will receive *Passiflora incarnata* Ø, and one will receive the placebo. The placebo does not contain any medication. Neither, you nor the researcher will know what medication you have received. The medication will be in liquid form and must be taken orally. You will be requested to dilute fifty drops of the medication in 20ml (4 tsp) of water. This should be taken twenty minutes before going to bed for four weeks. With this you will also receive a sleep diary, and you will be requested to complete it each morning. There will be a follow up visit at weeks two and four. You will be requested to bring along your sleep diary. At each consultation your vital signs: pulse rate, blood pressure, respiratory rate and temperature will be assessed for your well being. The duration of the study will be four weeks.

There are no anticipated side effects in taking the medication. However an allergic reaction can occur, but this is rare. In the event you experience any worrying symptoms stop taking the medication and contact the researcher immediately. If necessary you should contact your family doctor or health care provider. The significant benefit of the above study is an improvement of your sleep.

Your participation in this research study is voluntary, and you are free at any stage to refuse participation, or withdraw your consent, and this will in no way cause a disadvantage to you. Your privacy, confidentiality, human dignity and equality will be protected by the researcher. Please feel free to ask the researcher any questions pertaining to the research. On completion of the study all results and findings of the study will be available and accessible to you on request. A copy of this consent form will be signed and given to you.

I, the volunteer fully understand what this research entails, and any questions that I have will be directed to the researcher. I understand the procedures to be followed and I agree to abide by them. I agree that any information about my case can be used for discussion by the researcher and colleagues. I am aware that I can refuse participation at any time.

Signature: _____ Date: _____

Thank you!

I, the researcher have completely explained the techniques and purpose of the treatment used in this research. Any questions that may arise from the volunteers will be answered to the best of my ability.

Signature: _____ Date: _____

Supervisor: Dr E .M. Solomon

Cell: 082 264 8862

Work: 011-406 2477

Co- Supervisor: Dr J Bond

Tel no: 082 333 1812

The Researcher:

S Amiraj-Surujparsad: 084 311 4561

Appendix B

Insomnia Research Questionnaire

NAME: _____ **DATE:** ☐

AGE (years) : ☐ **MARITAL STATUS: S** ☐ **M** ☐ **D** ☐ **W** ☐

GENDER: M ☐ **F** ☐ **CHILDREN - NO:** ☐

CONTACT NO. (H)/ (W): ☐ **- AGES:** ☐

CELL NO: ☐

Please indicate by means of a cross ☒ which is applicable to you.

1) How long have you been suffering from Insomnia?

< 1wk	
1 – 2wks	
3 – 4wks	
2 - 3mths	
> 3mths	
Other, specify	

2) Do you find that you have a difficulty in falling asleep because you have an active mind?

YES	
NO	

3) What kind of thoughts go through your mind when trying to sleep?

Pleasant thoughts	
Stressful thoughts	
Worries	

4) How do you sleep?

Double bed with partner?	
Single bed in same room with partner?	
Alone?	

5) What time do you usually have dinner?

6) What is the specific time that you go to bed?

7) How long does it take you to fall asleep? Specific time?

	HOURS

8) Do you wake up at night?

YES	
NO	

9) How many times do you wake up at night?

10) What are the reasons for you waking up at night? (You can tick more than 1 block if applicable)

	Not a reason	Very Occasionally	Often	About every night
Noises				
Going to the bathroom				
Partners snoring				
Thirst				
Hunger				
Nightmares				
Mosquitoes				
Pets				
Children				
Other, specify				

11) How long does it take you to fall asleep again?

(Time minutes) ☐

12) What do you do while awake before falling asleep again?

☐

13) Within an hour before going to bed, do you have or do any of the following:

	YES	NO	
Alcohol:			If **YES**, how many glasses ☐
Caffeinated drinks (e.g.Coffee, tea)			If **YES**, how many cups ☐
Smoke cigarettes:			If **YES**, how many cigarettes ☐
Study:			
Watching TV:			
Reading:			
Having Sexual intercourse:			
Listen to music:			
Listen to the radio:			
Drink milk or water:			If **YES**, how glasses ☐
Other, specify:			

14) What time do you finally wake up in the morning?

	(Time, minutes)

15) How many hours do you sleep per night?

MIN	
MAX	

16) How do you wake up in the morning?

Alarm Clock	
Without any aid	
Pets	
Woken by partner or member of household	
Children	
Other, specify	

17) On waking in the morning, how do you feel?

Refreshed	
Tired	
Sleepy	
Confused	
Other, Specify	

18) How many nights a week is your sleep disturbed?

	Number of nights.

19) How have you been feeling emotionally recently (To eliminate depression)

Contented	
Happy	
Sad	
Depressed	
Other, Specify	

20) As far as you are aware do you experience any of the following during sleep?

Walking in your sleep?	YES ☐	NO ☐
Talking in your sleep?	YES ☐	NO ☐
Nightmares?	YES ☐	NO ☐
Other, Specify?		

21) Do you snore or have been told that you snore loudly while asleep?

YES	
NO	

22) Do you sometimes stop breathing during sleep? (To eliminate obstructive sleep apnea)

YES	
NO	
DON'T KNOW	

23) When in bed do your legs twitch and cause you to be restless (To eliminate restless leg syndrome)

YES	
NO	
DON'T KNOW	

24) Do you suddenly fall asleep during the day? (To eliminate narcolepsy)

YES	
NO	

25) Are you pregnant or breast feeding at this point in time?

YES	
NO	

26) Are you allergic to granadillas?

YES	
NO	

27) What medication are you taking at this moment in time? Please specify?

_____

28) Are you taking any sleeping tablets?

YES	
NO	

29) If **YES**, please specify the type of tablet?

_____

30) How many tablets are you taking? ☐

31) How often are you taking them? ☐

Drug history: _____
_____
_____

Medical history: _____
_____
_____

If participants answer **YES** to questions 20, 22, 23, 24, 25, 26 and **depressed** to question 19, they will not qualify for the above study.

Physical examination: Vital Signs

Temperature: _____
Blood pressure: _____
Pulse rate: _____
Respiratory rate: _____

Appendix C

Patient Diary

Date	Time	Time falling asleep	Satisfaction with Sleep (1-5)	What did you do/ have 1hr/s before bed?									No-of-Hours-Slept	Final time of waking	Have you noticed any change in sleep pattern?			Have you taken any medication to help you sleep?			Signature
				Reading	Studying	Watch TV	Having a bath	Alcohol	Caffienated drinks	Smoke	Emotional Upsets	Sexual Intercourse			Yes	No	If Yes, specify	Yes	No	If Yes, specify	

Satisfaction with Sleep: Score on a rating of 1-5

1 - Difficulty waking up
2 - Unrefreshed
3 - Tired
4 - Alert
5 - Alert and Refreshed

Appendix D

Follow up Form

NAME: _____

DATE: [ ]

Please indicate by means of a cross ☒ which is applicable to you.

1) How are you feeling with regards to your sleep?

Having a difficulty waking up?	
Unrefreshed?	
Tired?	
Alert?	
Alert and Refreshed?	

2) Have you noticed any changes in your sleep pattern, since taking the medication?

YES	
NO	

3) If **YES**, please specify?

[ ]

4) What time did you go to bed last night?

[ ]

5) How many hours of sleep did you get last night?

[ ] **Hours of sleep**

6) How many times do you wake up during the night?

[ ]

Physical examination: Vital Signs

Temperature: _____
Blood pressure: _____
Pulse rate: _____
Respiratory rate: _____