The Efficacy of *Coffea cruda* 200cH on Insomnia

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DECLARATION

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

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ABSTRACT

Insomnia is defined as inadequate sleep due to difficulty falling asleep, difficulty staying asleep, waking up too early, and not being able to get back to sleep. In Western industrialised nations, between 30% and 40% of individuals suffer from at least occasional periods of sleep disturbance. The significance of sleep lies in its impact on the Central Nervous System as extended periods without sleep will result in disturbances in mental function.

The remedy used in this study was Coffea cruda 200cH. This homoeopathic remedy is used clinically for its sedative and calming effect on the nervous system, in the homoeopathic treatment of insomnia. Although there is some research evidence that Coffea cruda has an effect on sleep in animals, there is no research on its effect on human subjects.

The aim of this study was to determine the efficacy of a homoeopathic remedy Coffea cruda 200cH in the treatment of insomnia that is characterised with a difficulty in falling asleep. The quality of sleep was assessed in terms of duration of sleep, changes in sleep pattern, and satisfaction with sleep.

This was a double blind placebo controlled study. The duration of the clinical trial lasted for four weeks. A total of thirty participants, meeting the inclusion criteria (Appendix B) were recruited via advertisements (Appendix E) in local newspapers, pamphlets and emails, sent in and around the University of Johannesburg Health Clinic, the University of Witwatersrand Sleep Unit, campuses, shopping malls and residential areas. Participants were also recruited via advertisements on a local radio station. At the initial consultation the participants were requested to sign a consent form (Appendix A). The researcher then completed the questionnaire (Appendix B) to assess suitability for the study. Participants were given a 50ml bottle of medication in liquid form, and were requested to shake the bottle and then take ten
drops under the tongue just before going to bed, for four weeks. A homoeopathic pharmaceutical company blinded the medication. By selecting a medication, the participant automatically allocated themselves to either the experimental or control group. Participants were also given a sleep diary to be completed every morning (Appendix C). There were follow up visits with participants on the second and fourth week where the sleep diary was checked to improve compliance and a case history was taken (Appendix D). All results were compared to the initial assessment and changes were recorded. Data were analysed according to the General Linear Model: Repeated Measures, Mann-Whitney test (non-parametric test), Cross-tabulation, Fisher’s exact test and Regression Analysis.

Statistical data proved that both the experimental and control groups had statistically significant results. It is unclear why the control group behaved in the same way as the experimental group. A longer trial is required to distinguish if this was purely due to the placebo effect.
DEDICATION

“In the Name of Allah, the Most Gracious, the Most Merciful”

All praises are due to my Creator for everything that has made this possible

To my late grandfather, Yussuf Nazeer.
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CHAPTER ONE

INTRODUCTION

1.1 Problem statement

The sleep regulation system comprises the homeostasis and circadian rhythm processes. Insomnia occurs when this system is affected by several psychological, environmental or physiological factors (Vallieres et al, 2005). Insomnia is defined as inadequate sleep due to difficulty falling asleep, difficulty staying asleep, waking up too early and not being able to get back to sleep (NAICS, 2005).

In Western industrialised nations, between 30% to 40% of individuals suffer from occasional periods of sleep disturbance (Pigeon and Sateia, 2004). Chronic insomnia is estimated to affect at least 10% of the adult population (Vallieres et al, 2005). On average, 1 in 20 individuals suffering from chronic insomnia will consult a physician specifically about the problem. Of individuals suffering from chronic insomnia, 25% will raise the problem during the course of a visit for other problems. Between 65% to 70% of individuals resort to over the counter medication options and alcohol to manage the condition (Pigeon and Sateia, 2004). According to a US-based study, examining the performance of general practitioners in assessing and managing patients with insomnia, 53% of physicians neglected to elicit any sleep history. After asking a mean of only 2.5 questions, 46% of physicians identified a prescription medication as the best therapy (Holbrook et al, 2000).

A prescription of hypnotic medication is the most common therapeutic intervention (Pigeon and Sateia, 2004). Benzodiazepines form a major part of treatment of sleep disorders and acute anxiety stress. They are known to have anxiolytic, hypnotic, muscle relaxant, anticonvulsant and amnesic actions (Neal, 2003). A high risk of
motor vehicle accidents, falls and fractures, fatal poisonings and a decline in functional status are some of the adverse effects associated with the use of benzodiazepines (Holbrook et al., 2000). Individuals taking benzodiazepines for even short periods may develop dependence and experience a physical withdrawal syndrome. These symptoms may persist for weeks or months, and include anxiety, insomnia, depression, nausea and perceptual changes (Neal, 2003). Barbiturates are far more depressant than benzodiazepines, and a small overdose may be fatal (Neal, 2003). If prolonged pharmacological treatment of insomnia is undertaken, the individual may begin to establish a hypnotic-dependent sleep disorder (Zorick and Walsh, 2000).

Individuals suffering from insomnia complain of impaired daytime functioning, fatigue, sleepiness, depression, anxiety and other mood changes due to poor sleep (Dement et al., 1989). Kupfer and Reynolds (1997) state that effective treatment of insomnia may prevent major depression, since persistent insomnia is a risk factor, and often a precursor of mood disorders. They also state that chronic insomnia merits serious attention, since it is associated with an increased risk of automobile accidents, increased alcohol consumption and excessive daytime sleepiness. Individuals with insomnia also have an increased risk of making mistakes, and report more absenteeism at work than do persons who sleep well (Leger et al., 2006). A person may become irritable, discontented, aggressive or even psychotic after forced wakefulness for prolonged periods (Guyton and Hall, 1996), (Langen, 1978).

*Coffea cruda* 200cH is a homoeopathic remedy which is commonly prescribed by homoeopathic clinicians in the treatment of insomnia (Gibson, 1987). However, research using the homoeopathic remedy in the treatment of insomnia has thus far only been conducted on rats, and is still in need on human subjects. According to Nash (2003), *Coffea cruda* may be helpful in treating individuals suffering from insomnia. It has a sedating effect, with the usual result of sleep that is restful and
invigorating. There have been no adverse effects noted after using the remedy (Tyler, 1995).

1.2 Aim of study

The objective of this study was to determine the efficacy of a homoeopathic remedy *Coffea cruda* 200cH in the treatment of insomnia that is characterised with a difficulty in falling asleep. The quality of sleep was assessed in terms of duration of sleep, changes in sleep pattern, and satisfaction with sleep.

1.3 Null Hypothesis

It is anticipated that the homoeopathic remedy *Coffea cruda* 200cH will not be effective in the treatment of insomnia.

1.4 Hypothesis

It is anticipated that the homoeopathic remedy *Coffea cruda* 200cH will be effective in the treatment of insomnia.

Statistical results are significant at a P-value of 0.05 or less. If the results of this study meet these requirements, the hypothesis cannot be rejected.
CHAPTER TWO

LITERATURE REVIEW

2.1 Sleep

Sleep can be defined as a physiological state of unconsciousness from which the person can be aroused by sensory or other stimuli (Guyton and Hall, 1996). The need for sleep is a biological drive similar to hunger and thirst. Adequate quantity and quality of sleep must be met in order to function appropriately in daily life (Gyllenhaal et al, 2000). There are 2 different types of sleep: rapid eye movement (REM) sleep, and non-rapid eye movement (NREM) or slow-wave sleep (Ganong, 2003), which can be differentiated by an electroencephalogram (EEG) (Rajput and Bromley, 1999).

2.1.1 NREM sleep

NREM sleep, also known as slow-wave sleep, is divided into 4 stages:

- Stage 1: a person first enters stage 1, which is characterised by a low threshold for arousal. This can also occur during stage transitions. In good sleepers, very little time is spent in stage 1, and the brain rapidly moves into stage 2.
- Stage 2: NREM has a much higher threshold for arousal and continues for 10 to 25 minutes after stage 1. The sleeper experiences a decrease in muscle tone, a lack of eye movements, and there are distinct EEG changes such as the appearance of sleep spindles. These sleep spindles are bursts of alpha-like waves. Alpha waves are found in the EEGs of normal adult people when they are awake in a quiet, resting state of cerebration.
- Stages 3 and 4: are usually grouped together, and are characterised by deep sleep. They comprise 13% to 23% of normal sleep time. This is considered to be the
deepest phase of sleep, where muscle tone is low and the EEG displays large slow waves. This is also known as the restorative phase of sleep, where anabolic hormones are secreted. Slow wave sleep is increased after situations of increased body catabolism during the day, such as exercise (Gyllenhaal et al., 2000), (Ganong, 2003), (Bentley and Berk, 2002).

NREM sleep is more restful than REM sleep. There is a decrease in peripheral vascular tone and many other vegetative functions of the body (Guyton and Hall, 1996). During NREM sleep, activity at the cerebral cortex is at a minimum. In addition, there is up to a 30% decrease in heart rate, blood pressure, respiratory rate and the basal metabolic rate (Martini, 1998).

2.1.2 REM sleep

NREM sleep is followed by a desynchronised sleep phase, also called REM sleep, which is characterised by the occurrence of rapid eye movements (Langen, 1978). Apart from the eye movements, muscle tone throughout the body decreases markedly. Active dreaming occurs, accompanied by an alteration in blood pressure. Heart rate and respiratory rate become irregular. During REM sleep, the overall brain metabolism may be increased by as much as 20%. The brain is highly active, and the EEG is similar to that of the waking person. This brain activity, however, is not channelled in the proper direction for a person to be conscious of their surroundings, and therefore to be awake (Martini, 1998), (Guyton and Hall, 1996), (Bentley and Berk, 2002). The first period of REM sleep occurs at 80 to 100 minutes after the person falls asleep (Guyton and Hall, 1996).

Alternation between NREM and REM sleep occurs at 90 to 110 minutes in 4 to 6 episodes during sleep. The structure of sleep is disrupted when the sleep period is shortened or an inadequate amount of time is spent in Stages 3 to 4 of NREM sleep.
Inadequate time spent in REM sleep also results in a disruption of sleep structure (Gyllenhaal et al, 2000), (Ganong, 2003).

The major significance of sleep lies in its impact on the central nervous system (Martini, 1998) as the periods of prolonged wakefulness are often associated with progressive malfunction of the central nervous system and at times, abnormal behavioural activities. A person may become irritable, discontented, aggressive or even psychotic after forced wakefulness for prolonged periods (Guyton and Hall, 1996), (Langen, 1978).

2.2 Insomnia

2.2.1 Definition and Description

Insomnia is defined as inadequate sleep due to difficulty falling asleep, difficulty staying asleep, waking up too early and not being able to get back to sleep. Patients suffering from insomnia often wake up feeling unrefreshed (NAICS, 2005). Insomnia is the perception by patients that their sleep is inadequate or abnormal. A conclusion at the Consensus Development Conference held by the National Institute of Mental Health in 1983, stated that insomnia is not a disease itself, it is a symptom (Dement et al, 1989).

Insomnia is divided into 2 subtypes:

- Acute or transient insomnia. This type of insomnia lasts for less than 3 weeks and is usually stress-related. Most of these resolve spontaneously; however, in some cases these short-term disturbances may evolve into chronic conditions and establish the biologic and behavioural cycle which is known as chronic insomnia.

- Chronic persistent insomnia. In this case insomnia lasts for longer than 3 weeks, and is associated with numerous medical, psychosocial, and circadian disturbances. The insomnia is considered secondary when these precipitating
factors play a significant role in the onset or maintenance of the sleep disturbance. In approximately 15% to 20% of chronic insomnia cases, there are no other diagnosable conditions directly associated with the insomnia. A diagnosis of primary insomnia then applies (Dement et al, 1989), (Kupfer and Reynolds, 1997), (Pigeon and Sateia, 2004).

There is no standard definition of insufficient sleep, because the amount of sleep required for a feeling of restfulness varies among individuals (Lacks, 1987), (Holbrook et al, 2000).

Insomnia does not necessarily occur every night. Vallieres et al (2005) conducted a study on the variability and predictability in sleep patterns of chronic insomniacs. They concluded that there is extensive variability in the sleep of individuals suffering from chronic insomnia, and that poor sleep may be predictable for some of them.

2.2.2 Incidence, Epidemiology and Demographics

In Western industrialised nations, between 30% to 40% of individuals suffer from at least occasional periods of sleep disturbance (Pigeon and Sateia, 2004), with insomnia being the most common of all sleep disturbances (NAICS, 2005). Chronic insomnia is estimated to affect at least 10% of the adult population (Vallieres et al, 2005). Although insomnia affects individuals of nearly every demographic, complaints of insomnia increase with age, and more women are affected with the condition (NAICS, 2005), (Kupfer and Reynolds, 1997). Zorick and Walsh (2000), state that women are 1.3 times more likely to report insomnia-like sleep problems than men.
2.2.3 Aetiology and Precipitating Factors

The sleep regulation system comprises of the homeostasis and circadian rhythm processes. Insomnia occurs when this system is affected by several psychological, environmental or physiological factors (Vallieres et al., 2005).

During sleep, a normal individual encounters several short awakenings of which they have no clear consciousness. If during the short period of waking, some factor causes anxiety or anger, there is then a progression to full awakening and remembering this awakening in the morning. In many cases subjects check the time on awakening, remember it and repeat this cycle many times throughout the night. The result is anger and frustration which delay return to normal sleep, and may promote subsequent awakenings (Nutt and Wilson, 2005). Individuals then develop maladaptive strategies in an attempt to get more sleep. This contributes to perpetuating factors in the evolution of a long-term problem. Spending excessive time in bed and staying in bed while awake are the most common of these maladaptive behaviours. This practice is thought to interfere with the regulation of the sleep homeostatic drive and reinforces wakefulness in bed through a classical conditioning paradigm, where the bed becomes associated with wakefulness, rather than sleep (Carney and Edinger, 2006), (Pigeon and Sateia, 2004).

In some individuals, there is a difficulty initiating sleep due to conditioned arousal. This is often due to anxiety about falling asleep and lack of confidence in the individual’s ability to fall asleep. The individual becomes increasingly alert, and this further inhibits the ability to fall asleep, and therefore increases the anxiety. The cycle eventually becomes self perpetuating and difficult to break. While lying in bed, the individual is very alert, and experiences thoughts moving very rapidly through the mind (Bentley and Berk, 2002).
Factors precipitating insomnia involve the following:

2.2.3.1 Psychological factors, where there is hyperarousal such as stress

Stress is defined as a natural arousal reaction and can have any combination of affective, cognitive, and biological components (Dement, et al, 1989), (Shapiro et al, 1994). If the source of the stress is prolonged and/or uncontrollable, feedback mechanisms will fail in restoring the equilibrium. The stress response then becomes inadequate, with the eventual result of various pathological states including sleep and mood disorders (Van Reeth, et al, 2000). Acute or chronic stress is listed as one of the causes of insomnia (Kupfer and Reynolds, 1997). Sleep that is disturbed by stress is characterised by any combination of difficulty falling asleep, difficulty maintaining sleep, or awakening too early. Stress, whether positive or negative, is a subjective experience (Shapiro et al, 1994). In some individuals, stress-related transient insomnia may serve as the basis for the development of a persistent psychophysiological insomnia (Dement, et al, 1989).

2.2.3.2 Psychiatric disorders, such as depression and anxiety disorder

Insomnia may be the result of anxiety, depression, or other minor or major psychological stresses (Shapiro, et al, 1994). Duobinis et al (2004) conducted a study on the prevalence of sleep disturbances in out-hospital patients in Lithuania. They concluded that both anxiety and depression were associated with increased rates of reported insomnia, and that quality of life was worse in these patients. Sleep disturbance may persist even after other signs of depression have improved with pharmacological therapy (Quan, 2004). Furthermore, the presence of chronic insomnia increases the risk of the onset of major depression. Therefore, the association between chronic insomnia and psychopathology is well established (Bixler, 2005). Other psychiatric conditions that can cause insomnia or sleep
disruption include panic disorder, mania, acute psychosis, anorexia nervosa and post-traumatic stress disorder (Rajput and Bromley, 1999), (Shapiro, et al, 1994).

2.2.3.3 Pharmacological factors, including prescribed and non-prescribed drugs

A wide variety of medications have been implicated in the aetiology of insomnia. Among the most common medications that disturb sleep are beta-adrenergic blockers, corticosteroids, thyroid hormone replacement therapy, selective serotonin reuptake inhibitors, monoamine oxidase inhibitors, methyldopa, phenytoin and some chemotherapeutic agents. Anti-hypertensives, anti-depressants and oral contraceptives may also cause sleep disruption. (Rajput and Bromley, 1999), (Pigeon and Sateia, 2004), (Bentley and Berk, 2002).

2.2.3.4 Medical factors

Sleep impairment is common in many medical disorders, and may worsen symptoms in these conditions or even worsen the overall prognosis (Berry and Harding, 2004) (Quan, 2004). Nearly every medical disorder has an interaction with sleep (Berry and Harding, 2004). Disorders associated with pain, being the most common, cause sleep disruption (Bentley and Berk, 2002). Pregnancy may also contribute to insomnia (NAICS, 2005). This is often due to the nausea, backaches, nocturia and heartburn which pregnant women experience (Kantrowitz, 2006).

2.2.3.5 Disruption of circadian rhythm

Circadian stresses, such as jet lag, schedule change and shift work, are typical precipitants of insomnia (Zorick and Walsh, 2000). A circadian rhythm sleep disorder is characterised by a persistent or recurrent pattern of sleep disruption that results from a mismatch between the individual’s endogenous circadian sleep-wake system, and exogenous demands regarding the timing and duration of sleep (Bentley...
and Berk, 2002). There are two common circadian rhythm disturbances, namely, advanced sleep phase syndrome, which is associated with early bedtime and early awakening, and delayed sleep phase syndrome, which is associated with late bedtime and late awakening (Rajput and Bromley, 1999). A third circadian rhythm disorder is the irregular sleep-wake pattern, which is defined as a persistently variable and disorganised sleep-wake schedule. In this condition, there is complete loss of circadian rhythmicity (Dement, et al, 1989).

2.2.3.6 Recurrent nightmares and sleep terror disorder

Nightmare disorder usually occurs during REM sleep and is characterised by the repeated occurrence of frightening dreams that lead to awakenings from sleep. Sleep terror disorder is characterised by a repeated occurrence in the first half of the night, of sudden awakenings from sleep with a scream and increased motor and autonomic activity, as if terrified. These arousals take place during stage 4 of NREM sleep, and are familial (Bentley and Berk, 2002), (Kupfer and Reynolds, 1997).

2.2.3.7 Stimulants

Stimulants such as nicotine, caffeine and appetite suppressants may result in a sleep disturbance. Alcoholism is associated with significant sleep disruption, which may even persist for months after abstinence is initiated (Rajput and Bromley, 1999), (Bentley and Berk, 2002).

2.2.4 Other Sleep Disorders related to Insomnia

Other disorders related to insomnia include sleep related movement disorders, and Obstructive Sleep Apnoea (OSA).
Sleep related movement disorders consist of Periodic Limb Movement Disorder (PLMD) and Restless Leg Syndrome (RLS). PLMD is common in persons over the age of 65 years and is characterised by stereotypical movements at 20 to 40 second intervals during sleep. These limb movements may lead to brief arousals or prolonged awakening in sleep with the result of insomnia (Crawford, 2004), (Rajput and Bromley, 1999). Individuals who experience Restless Legs Syndrome (RLS) describe an uncomfortable sensation in the limbs that comes on at rest and is relieved by movement such as walking. This restlessness causes a delay in sleep onset. A high percentage of individuals suffering from RLS may also suffer from PLMD in sleep (Rajput and Bromley, 1999), (Pigeon and Sateia, 2004).

Obstructive Sleep Apnoea (OSA) is a chronic respiratory disorder that affects approximately 4% of men and 2% of women in the middle-aged (Crawford, 2004), (Douglas, 2005). Symptoms of OSA include loud snoring, choking or gasping episodes during sleep, and excessive daytime sleepiness which is due to poor night sleep (Rajput and Bromley, 1999). When individuals complain of recurrent awakening, with other signs and symptoms of OSA, one should consider the OSA as a precipitating factor of insomnia (Pigeon and Sateia, 2004).

2.2.5 The clinical effects of Insomnia

Patients suffering from insomnia complain of impaired daytime functioning, fatigue, sleepiness, depression, anxiety and other mood changes due to poor sleep (Dement et al, 1989). They also have an increased risk of making mistakes, and report more absenteeism at work than do persons who sleep well (Leger et al, 2006). Frey et al (2004) conducted a study on the effects of total sleep deprivation on inflammatory markers. They concluded that one night of acute total sleep deprivation will result in an alteration of circulating levels of pro- and anti-inflammatory immune cytokines and cellular adhesion molecules. According to Frey et al (2004), high circulating levels of pro-inflammatory cytokines and cellular adhesion molecules are known as
independent risk factors for cardiovascular disease. While sleep deprivation is associated with cardiovascular morbidity and mortality, the consequences of the findings of the study for immune function and/or cardiovascular disease during sleep deprivation remain to be determined.

Many of the signs associated with insomnia are not pathological, but are common complications of inadequate sleep or an alteration in the sleeping process. In recent years there is mounting evidence of certain measurable biological findings, which are found to be more common in individuals suffering from chronic insomnia. These include an elevation in heart rate, body temperature, basic metabolism and cortical EEG. Patients suffering from chronic insomnia have demonstrated elevated cortisol levels throughout a 24-hour period, and have not demonstrated any increased degree of sleepiness during the daytime. These signs are consistent with the overall state of both physiological and cognitive hyperarousal. These states of hyperarousal predispose to insomnia (Pigeon and Sateia, 2004), (Kales and Kales, 1984), (Bixler, 2005).

### 2.2.6 Diagnosis

A complaint of insomnia is diagnosed through a detailed personal history, a sleep history questionnaire including sleep and wakefulness patterns, and a structured sleep interview (Holbrook et al, 2000) (Lacks, 1987).

Most sleep laboratories, including the Glasgow Sleep Centre stress on the importance of the usage of a sleep diary. A sleep diary is a diary indicating the patients usual bedtime, time of rising, time of meals, alcohol intake, exercise, medications and descriptions of the duration and quality of sleep, which is recorded on a daily basis. These parameters reveal aspects of the individual’s lifestyle that can be destructive to sleep. Although sleep diaries collect subjective judgements of sleep, the sleep diary is nevertheless the most valid tool used to measure the essential feature of insomnia,
which is the individual’s complaint of poor sleep. Sleep diaries enable the gathering of information about the individual’s perception both of sleep disturbance and of recovery following treatment, and is standard practice in the assessment of behavioural sleep medicine (Kupfer and Reynolds, 1997), (Nutt and Wilson, 2005), (Malaffo and Espie, 2007), (Buysse, et al, 2006).

The following factors indicate disordered sleep: a variable sleep duration, variable sleep latency, extended sleep latency, restless sleep, and general dissatisfaction with sleep (Spiegel, 1981). According to Porth (2005), sleep latency is regarded as the duration of time that it takes for an individual to fall asleep.

2.3 Treatment of Insomnia

As concluded by the Consensus Development Conference held by the National Institute of Mental Health in 1983, that insomnia is not a disease but merely a symptom (Dement et al, 1989), initial treatment involves identifying and treating underlying causes (Rajput and Bromley, 1999), (Holbrook et al, 2000).

2.3.1 Pharmacological Treatment

2.3.1.1 Conventional Treatment

Pharmacological treatment involves the use of benzodiazepines, anti-depressants, barbiturates and melatonin.

Benzodiazepines form a major part of treatment of sleep disorders and acute anxiety stress. They are known to have anxiolytic, hypnotic, muscle relaxant, anticonvulsant and amnesic actions (Neal, 2003). Dependence may occur at therapeutic doses, and after only a few weeks of therapy (SAMF, 2003). Holbrook et al (2000), state that benzodiazepines should only be administered to patients after sleep hygiene and non-
pharmacological methods of treatment have been considered. When benzodiazepine therapy is required, treatment usually lasts for 2 to 4 weeks, as it is unlikely to remain effective in the long-term. Once treatment with benzodiazepines has stopped, individuals may commonly experience a rebound of symptoms associated with worsening of sleep disturbance for 1 or 2 nights. Individuals may also experience longer sleep onset latency and increased waking during sleep (Nutt and Wilson, 2005).

Tricyclic anti-depressants have a sedative effect and are useful in inducing and maintaining sleep (Neal, 2003). Overdose of tricyclic anti-depressants may lead to cardiotoxicity and anticholinergic effects. Anticholinergic effects include dry mouth, blurred vision, constipation and difficulty with micturition (SAMF, 2003). Despite these adverse effects, anti-depressants have been the drug of choice for many practitioners, for the treatment of insomnia in the United States (Walsh, 2004).

Barbiturates are far more depressant than benzodiazepines, and a small overdose may be fatal (Neal, 2003). The side effects of barbiturates include hypotension, respiratory depression and apnoea, laryngeal and bronchial spasm (SAMF, 2003).

Allopathic drugs used for insomnia have a schedule IV status due to their high risk of abuse and dependence. Patients are likely to develop tolerance to these sedatives (Walsh, 2004), (Crawford, 2004). Apart from adverse reactions, long-term use of many psychotropic or sedative hypnotic drugs may actually impair sleep. Pharmacological agents appear to act more reliably in the short run, but may not be as effective in the long term. Behavioural intervention thus provides more sustained effects (Kupfer and Reynolds, 1997), (Rajput and Bromley, 1999).
2.3.1.2 Alternative Treatment

The use of melatonin is considered as an alternative form of treatment for insomnia. In the body, melatonin is a hormone that is synthesized and released from the pineal gland and acts as a reliable marker of the circadian clock (Burgess and Eastman, 2006). Melatonin has shown to be helpful in the sleep disturbance of individuals with decreased endogenous melatonin (Pigeon and Sateia, 2004). However, it appears to be ineffective for individuals suffering from insomnia with normal melatonin levels. In such individuals, it seems to help in alleviating jet lag (Nutt and Wilson, 2005). Adverse effects of melatonin include proconvulsant effects in neurologically impaired children and vasoconstriction of cerebral arteries (Mendelson, 2000). Melatonin may also have anti-gonadotrophic properties, where it can inhibit ovulation by decreasing luteinizing hormone concentrations (Rajput and Bromley, 1999).

Herbal hypnotics are herbal remedies with the reputation of inducing sleep. Their effects range from mild muscle relaxation to remedies that contain strong alkaloids that work directly on the central nervous system (Hoffmann, 1993). These herbal remedies include:

- **Valeriana officinalis**: this herb consists of valerenic acid which offers substantial sedative potency, however, the effects of the herb tend to diminish with continued uninterrupted use (Anderson, 2001).
- **Passionflower**: is considered to be effective in the treatment of insomnia (Anderson, 2001).
- **Kava kava**: is helpful in the treatment of insomnia associated with anxiety (Anderson, 2001).

Supplements that encourage better sleep include vitamin B-complex, calcium and magnesium, and tryptophan. Chromium is also beneficial for individuals who are suffering with hypoglycaemia (Anderson, 2001).
2.3.2 Non-Pharmacological Therapy

This involves lifestyle changes, such as:

- Maintaining regular bedtimes and waking times.
- Reduced daytime napping.
- Exercising during the day with adequate exposure to sunlight.
- Avoiding stimulants such as alcohol and cigarettes in the evening.
- Avoidance of dwelling on problems in bed (Nutt and Wilson, 2005).
- Limiting time in bed to periods of sleep or sexual activity.
- Getting out of bed within 15 minutes if unable to fall asleep (Seppa, 1999).
- Keeping a sleep diary. This is beneficial in helping the individual to improve sleep hygiene (Rajput and Bromley, 1999).
- Regulating food and caffeine intake at bedtime (Anthony, 1998).

Stress management strategies are recommended where psychological arousal affects daytime functioning. Relaxation during the day is also encouraged (Riedel and Lichstein, 2000). This includes muscle relaxation, breathing exercises at bedtime, guided imagery, listening to quiet music and forms of meditation practice (Pigeon and Sateia, 2004), (Anderson, 2001).

A good diet is vital to overcoming insomnia. This involves eating foods rich in B vitamins, fruits, vegetables and fish. Dairy rich foods, salt and sugar intakes are avoided. Drinking eight glasses of water during the day may also prove beneficial to individuals suffering from insomnia (Tolin, 1997). Foods that enhance sleep have high tryptophan/tyrosine and tryptophan/phenylalanine ratios. These consist of a wide range of foods including pumpkins, bananas, nuts, eggs, liver and beans (Anderson, 2001).

Instead of individuals trying to sleep, they may engage in calming and restful activities such as reading non-stimulating material, or taking a warm bath.
Individuals may also eliminate the bedroom clock, regulate bedtime, and explore daytime napping only before 3p.m (Hauri, 1991), (Pigeon and Sateia, 2004).

Sleep hygiene behaviours form an important component of the treatment plan, but are unlikely to manage the sleep problem as the sole mode of treatment (Zorick and Walsh, 2000).

2.4 Homoeopathy

2.4.1 Introduction

Homoeopathy is a system of medicine, which was founded by the German physician Dr. Samuel Hahnemann (1755-1843). This form of medicine is based on the principle “Similia Similibus Curentur”, meaning, “like cures like”, which is also known as the law of similars (Sankaran, 1995).

Dr. Samuel Hahnemann obtained a degree in medicine at the Frederick Alexander University in Erlangen, in August 1779. He then took up a medical officer of health post in a town called Gommern. During the time of his practice, diseases of the body were fought with methods such as blood-letting, purgatives, emetics, leeches as well as large quantities of chemicals such as arsenic and mercury. These methods of treatment, as well as repeated venesection, led to his dismay at contemporary methods of treatment at the time. With the result, he finally withdrew from medical practice (Kayne, 2006), (Vithoulkas, 1981), (Gunavante, 2005).

During the time of Dr. Hahnemann, Cinchona bark was used to treat malaria. In 1790, Hahnemann discovered that when a healthy individual took Cinchona, it produced symptoms in the individual similar to those of malaria. He then began to test a number of drugs on himself and some volunteers. He wanted to determine the effects that these drugs could produce on healthy individuals, so that he could use the
same drugs on sick individuals who presented with the same symptoms. After 6 years of experimentation, he came to the realisation and conclusion that the positive effect of these drugs on a healthy individual cured the same picture in a diseased individual. By using this method to cure a diseased individual, the presenting symptoms of the patient are matched with the symptom picture of the remedy, thus stimulating the vital force of the individual, to bring about cure. (Sankaran, 1995), (Kayne, 2006), (Gunavante, 2005), (Vithoulkas, 1981).

2.4.2 Principles and Practice of Homoeopathy

Homoeopathic treatment is based on certain principles that have been brought about by Dr. Hahnemann. Among these principles are the law of similars, the law of administering a single remedy and the law of using the minimum dose in treating an individual (Varma and Vaid, 2001).

According to the law of similars, a medicine which is capable of producing certain effects when taken by a healthy human being, is capable of curing any illness that displays similar effects (Sankaran, 1995). The law of similars involves prescribing a homoeopathic remedy that bears symptom similarity with the complaints of the individual (Watson, 1999). This is the most fundamental law of homoeopathic treatment (Gunavante, 2005).

Dr. Hahnemann encouraged the law of administering a single remedy on the basis that the actions of remedies have only been proved on a single remedy at a time. By administering more than one remedy to an individual at a given time, one is not aware which of the remedies have had an effect on the individual (Kayne, 2006), (Gunavante, 2005).

In aphorism 154 of the organon, Dr. Hahnemann also mentions the law of the minimum dose, where any illness can be cured by a single dose of the homoeopathic
remedy, provided the symptom picture of the homoeopathic remedy specifically matches the symptom picture of the diseased individual (Hahnemann, 2001).

According to homoeopaths, disease in an individual is considered to be an expression of the vital force. The vital force is considered as the body’s natural defence mechanism comprising the Reticulo-Endothelial System (RES) and the Psycho-Neuro-Endocrine System (PsNES). In a healthy individual, the vital force is thought to be responsible for keeping the body’s function in harmony and for coordinating the body’s defence against disease (Gunavante, 2005), (Kayne, 2006). Thus, disease is not due to an affection of the body’s organs. Disease within an individual occurs due to a disturbance of the vital force (Sankaran, 1995). The action of the prescribed homoeopathic remedy then strengthens the body’s defence mechanism which in turn corrects this disturbance of the vital force (Varma and Vaid, 2001).

Homoeopathic remedies are generally considered to be safe. Nevertheless, certain individuals may experience a healing or remedy reaction known as an aggravation (Kayne, 2006). Due to the fact that a homoeopathic remedy will produce similar symptoms when administered to a healthy individual, it can be expected that it will produce the same symptoms in a sick individual as well. Thus, a truly curative response may be preceded by some degree of an aggravation of symptoms, and this response is welcomed by many homoeopaths as part of the process of cure (Vithoulkas, 1981).

Homoeopathic treatment can cause 3 types of aggravations:
1. Homoeopathic aggravation: the individual experiences an increase in symptoms, but feels better in themselves.
2. Medicinal aggravation: the individual being treated develops a new symptom characteristic of the remedy.
3. Disease aggravation: there is no improvement and the disease progresses. (Kayne, 2006).
The aggravation of symptoms may be very slight and may last only briefly. If the aggravation of the individual’s symptoms, however, becomes marked or prolonged, the individual would then be proving the medicine (Cook, 1989).

From Dr. Hahnemann’s experience in practice, an aggravation of symptoms was maintained with homoeopathic remedies administered in low potencies or crude form. Homoeopathic remedies administered in high potencies are considered safe and unlikely to provoke any aggravation in the individual being treated. When the dose however, is administered for a prolonged period, the individual may experience a severe and prolonged aggravation. Thus, it can be said that a homoeopathic remedy may be beneficial or harmful depending on the frequency administered to the individual. In the case of an aggravation, it is advised that the homoeopathic remedy be stopped immediately (Kayne, 2006), (Varma and Vaid, 2001), (Cook, 1989).

2.4.2.1 Indications for homoeopathic treatment

Homoeopathy can be used as a first option in the treatment of certain problems, and many diseases can be successfully treated with homoeopathic remedies (ECH, 1998). Homoeopathic treatment can also be utilised in cases where allopathic medicines appear to be losing their effectiveness over time, and where individuals are using the same over the counter medication for a specific disease for a prolonged period of time (Kayne, 2006).

2.4.2.2 Potencies and preparation of homoeopathic medicines

Homoeopathic medicines are often called remedies and are of botanical, chemical, mineral, zoological or microbiological origin (Wiegant, et al, 1998). In order to prepare a homoeopathic medicine, the crude substance needs to be made amenable for potentization. This involves making the mother tincture. The mother tincture is then diluted with 40% alcohol to 1 in 10 or 1 in 100. The Decimal scale is
designated by the letter ‘x’ or ‘D’ and is represented as 1 in 10 (1:10). The Centesimal scale is designated by the letter ‘c’ or ‘cH’ and is represented as 1 in 100 (1:100). If the crude substance is insoluble in alcohol, it needs to go through a method called trituration, where it is ground continually in lactose until it becomes soluble in alcohol. Once diluted the mixture then undergoes a process called succussion, where it is shaken vigorously between 10 and 100 times per minute. This produces the first potency, which is the 1x or 1cH. To produce the next potency, one part of the first potency is taken and diluted again in alcohol to 1 in 10 or 1 in 100, and succussed as before, to produce the 2x or 2cH potencies. Successive serial dilutions follow until the solution reaches 12cH, 30cH, 200cH and so on, using fresh glass vials at each stage. As the potency of a substance is increased the solution becomes more dilute but is nevertheless said to act more effectively (Kayne, 2006), (Souter, 2001), (Lockie and Geddes, 1995), (Vithoulkas, 1981).

2.4.3 Homoeopathic treatment of insomnia

When prescribing a homoeopathic remedy for insomnia, a full case history is taken from the individual. The most characteristic symptoms of the individual will then be used to find a remedy that matches the totality of symptoms of the individual (Kayne, 2006). There are some remedies that have insomnia strongly expressed in their symptom picture. Examples of these are:

- **Nux Vomica**: this remedy is indicated for individuals suffering from insomnia who are able to fall asleep, but awaken between 3am-4am with an overactive mind, full of worries. This type of insomnia is often the result of the individual who has taken various drugs for their complaint and has chronic indigestion.

- **Aconite**: this remedy is indicated for acute insomnia where the individual is restless and anxious.
• **Chamomilla**: the individual requiring this remedy is very irritable and suffers from insomnia in the early part of the night. These individuals are sleepy during the day but are unable to sleep at night. This remedy is also indicated for teething infants who are unable to sleep.

• **Cocculus**: individuals who have stayed awake all night to nurse patients and suffer from insomnia due to exhaustion often require this remedy. They awake feeling unrefreshed in the morning and are drowsy during the day.

• **Gelsemium**: excitement and anticipation of an upcoming event keeps the individual awake. The individual however, is dull, drowsy and may even be trembling.

(Vermeulen, 2001), (Dooley, 2004), (Hering, 1994), (Boericke, 2003).

### 2.4.4 Homoeopathic research conducted on insomnia

Research conducted by Roohani (1998) using Avena Sativa Comp® helped decrease fatigue and evening sleepiness, and improved the subjects perception of the quality of their sleep. A total of 10 participants entered a double blind crossover trial, consisting of 14 days on a placebo and 14 days of taking the homoeopathic complex, which was administered nightly. Avena Sativa Comp® helped to decrease fatigue and evening sleepiness. The complex also improved the participants’ perception of the quality of their sleep. Substances in Avena Sativa Comp® suggest that it may be an effective, non-addictive alternative to hypnotics, particularly in the treatment of insomnia caused by frequent arousals.

Pellow (2002) conducted a study on homoeopathic similimum treatment of secondary insomnia in peri- and postmenopausal treatment of women, over 3 months. Out of 10 participants, 7 had an amelioration of the insomnia symptoms. They also reported an increase in total sleep time, a decline in the number of nightly wakenings, improved
perception of quality of sleep, and a decrease in sleep onset latency. These participants also noticed a decrease in daytime sleepiness and improved energy levels. These effects were due to the similimum remedy identified. The other 3 participants did not have successful outcomes since identifying the optimal similimum remedy was not immediate. These participants thus had a slight aggravation of their insomnia symptoms and did not experience a sense of complete well-being.

Guadalupe and Jose-Leonel (1997) conducted a study using *Nux vomica* 30cH on the sleep pattern of rats. They argued that the placebo effect could be avoided by administering a homoeopathic remedy to rats, thus enabling the true action of the remedy to be observed. They also felt that a study of this nature could provide a scientific basis for the practice of veterinary medicine. The homoeopathic effect to be achieved was to be characterised in physicochemical terms, based on the analysis of electrical signals from different parts of the body. Thus, results were recorded using EEG monitoring during the sleep period of the animals. The researchers were also observing if any systematic and reproducible changes resulted from the administration of the homoeopathic remedy. The results displayed enhanced variability of the EEG after the homoeopathic stimulus was applied, which in turn reflected an unstable pattern due to irritation of the central nervous system by the homoeopathic medicine. According to the Materia Medica, *Nux vomica* does cause irritation of the central nervous system of healthy human subjects, thus correlating the findings of the study to the Materia Medica. Changes in systematic behaviour were also noted, and this too correlated to the symptoms of the Materia Medica.

### 2.4.5 *Coffea cruda*

*Coffea cruda*, also known as *Coffea arabica*, belongs to the botanical order Rubiaceae. The source of *Coffea cruda* is the raw coffee bean. (Gibson, 1987), (Parrotta, 2001). The plant is native to Ethiopia and Sudan and consists of small
berries that are fleshy and dark purple when ripe (Parrotta, 2001). The raw coffee bean is utilised in making the homoeopathic remedy, since roasting destroys the caffeine and changes it into caffeone (Hering, 1994). The constituents include caffeine, coffee oil, trigonelline, volatile oils, tannins, sucrose and other sugars, proteins, chlorogenic and caffeic acids, niacin/nicotinic acid (Vermeulen, 2002).

Due to its high content of the alkaloids caffeine and theobromine, coffee has a stimulating action on the central nervous system (Hoffmann, 1991), (Nash, 2003). These involve functional disturbances such as headache, vertigo and palpitations. It increases mental activity, produces insomnia and great nervous restlessness. Caffeine reduces the feeling of fatigue, improves concentration and a clearer flow of thought (Vermeulen, 2002). The neuromuscular system is affected, with the result of twitching and tremors. Heart rate and cardiac output are increased, and vasodilatation of peripheral vessels occur which result in a diuretic effect (Gibson, 1987). In Ayurveda, the leaf and seed of this plant are used to treat cardiac diseases, dysentery and headache, among other illnesses (Parrotta, 2001).

Ruiz-Vega et al (2002), conducted a study on the comparative effect of Coffea cruda potencies on rats. The effects of Coffea cruda 30cH, Coffea cruda 200cH and caffeine were investigated on the sleep pattern of rats. Subjects received the treatment orally at the beginning of the sleep period. EEG recordings were taken and analysed. They concluded that Coffea cruda 200cH had an effect only on the synchronization of sleep, while Coffea cruda 30cH and caffeine had similar positive effects on the sleep pattern.

In another study conducted by Ruiz-Vega et al (2000), Coffea cruda 30cH was administered to the rats at the beginning of their waking period. As this was a double blind study, 30 young adult male Wistar rats received either Coffea cruda 30cH or drinking water. EEG recordings, specific to NREM changes, were then taken during their next sleep cycle through a 7-hour period. The effect of Coffea cruda was
associated with an enhancement in slow-wave delta activity. Thus, *Coffea cruda* displayed an enhancement on NREM sleep.

In (2003), Riuz-Vega *et al* conducted a study on the biological effect of *Coffea cruda* 30cH in male Wistar rats, which received caffeine pre- and post-treatment. In the pre-treatment group, caffeine was administered to the rats intraperitoneally at the beginning of a sleep period. 30 minutes later, *Coffea cruda* 30cH was administered orally. In the post-treatment group, caffeine was administered to the rats 1 hour after administering *Coffea cruda* 30cH. A control group was tested simultaneously in both the pre and post-treatment groups. EEG recordings were taken during the following sleep cycle. At the end of the clinical trial, the researchers concluded that in the group that received caffeine pre-treatment *Coffea cruda* 30cH had modified sleep pattern which resulted in increased sleep intensity. In a subset of rats, which received caffeine post-treatment, *Coffea cruda* 30cH appeared to reinforce the effects of caffeine. According to the researchers, this occurred due to an aggravation of the homoeopathic remedy.

Apart from insomnia, *Coffea cruda* as a homoeopathic remedy has an ability to treat a wide variety of symptoms such as neuralgia, nervous palpitations and convulsions in children due to teething (Hering, 1994) (Vermeulen, 2001).

*Coffea cruda* is considered to be beneficial in the treatment of insomnia, where there is an overactive brain, accompanied by hypersensitivity to external stimuli (Gibson, 1987). The individual is restless and cannot get to sleep due to a flow of ideas going through the mind (Hering, 1994). These flow of ideas keeps the individual awake with no inclination to sleep at all (Moiloa, 2000). When taken homoeopathically, *Coffea cruda* is believed to have a sedative action and it is thought to result in sleep that is restful and invigorating with no adverse effects (Tyler, 1995).
According to Varma and Vaid (2001), *Coffea cruda* administered in a mother tincture and low potencies may result in an aggravation involving rapid and irregular heartbeats, elevated blood sugar and cholesterol levels, excess stomach acid and heartburn. The individual may also experience nervousness and insomnia. Nash (2003) suggests that *Coffea cruda* be used in the 200 potency for the treatment of insomnia.
CHAPTER THREE

METHODOLOGY

3.1 Study Design

This was a double blind placebo-controlled study, which took place over a period of 4 weeks at the University of Johannesburg Health Clinic. The medication was manufactured and blinded by Natura Laboratories who assigned numbers to the treatment bottles. Neither the researcher, nor participants were aware of which group they belonged to. By selecting a bottle of medication, the participant automatically allocated themselves to either the experimental or control group. The study was unblinded after the completion of the clinical trial.

3.2 Study Sample

The study was conducted on 30 participants, males and females, between the ages of 18 and 50 years, suffering from insomnia. A total of 30 participants were recruited via advertisements (Appendix E) in local newspapers, pamphlets and emails sent in and around the University of Johannesburg Health clinic, the University of the Witwatersrand Sleep Unit, campuses, shopping malls and residential areas. Participants were also recruited via advertisements on a local radio station.

3.2.1 Inclusion Criteria

- Participants suffering from insomnia for no longer than a year.
- Insomnia that participants experienced had to be associated with nervous excitability which manifested as a difficulty in falling asleep.
3.2.2 Exclusion Criteria

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

3.3 Research procedure

The researcher met with people responding to the advertisements. On initial consultation, the participant was requested to sign a consent form (Appendix A) and the researcher then completed the initial questionnaire (Appendix B). Based on the questionnaire (Appendix B), and inclusion and exclusion criteria, it was determined which participants qualified for the above study.

Participants received a 50ml bottle of medication in liquid form, and were requested to shake the bottle and then take 10 drops under the tongue just before going to bed, for 4 weeks. Participants were also given a sleep diary, and were shown how to complete it every morning (Appendix C). Participants were allowed to take over the counter medication if insomnia became extreme, in which case they had to indicate which medication they had taken, and the day on which they had taken it, in their sleep diary (Appendix C) provided to them. These data were then excluded in the final data analysis.

After the initial consultation, an appointment was made with the participant for a follow up visit on the second and fourth week. Sleep diaries were checked to
promote compliance and case histories were taken at week 2 and week 4 respectively (Appendix D).

3.4 Data collection

At the end of the clinical trial, an appointment was made with the participant and the researcher collected all the sleep diaries.

3.5 Data analysis

All the relevant data were analysed according to the General Linear Model: Repeated Measures, Mann-Whitney test (non-parametric test), Cross-tabulation, Fisher’s exact test and Regression analysis. Data were represented in the form of descriptive statistics, bar graphs and line graphs (Steffens, 2007).

3.6 Reliability and validity measures of the study

Quality of data and reliability were improved through a sleep diary (Appendix C), which is a standard procedure in insomnia studies. Questions in the sleep diary served as a measurement of the parameters of the study. All participants were given exactly the same sleep diary (Appendix C), which was evaluated at each follow up consultation. A standard case history (Appendix D) was also taken at each follow up. All results were then compared according to the initial assessment and any changes were recorded. The initial questionnaire (Appendix B) and sleep diary (Appendix C) were drawn up in consultation with the statistician, Professor F.E Steffens (2007) and the University of the Witwatersrand Medical School Sleep Unit. The questionnaire (Appendix B) is a modified version of the Sleep Disorders Questionnaire (Violani, 2004). It is a standard procedure at the University of the Witwatersrand Medical School Sleep Unit to modify the sleep questionnaire and sleep diary according to their specific study.
3.7 Ethical considerations

The study was approved and passed by the University of Johannesburg Faculty of Health Sciences Academic Ethics Committee and Academic Higher Degrees Committee on the 18th August 2006. The Ethics Clearance number is 29/06.

Details of the study were fully explained to each participant prior to signing the consent form. As mentioned in the consent form, participants were informed that their participation in the study was completely voluntary and that they were free to withdraw at any stage.

Participants were made aware of the significant benefit and an advantage of the study being an improvement in sleep. Participants were also informed that there were no risks of the above study, however, should any adverse reaction occur, participants would stop the study and be referred to their doctor or health care provider.

All information pertaining to participants were kept strictly confidential and only the researcher and supervisors have had access to it. The researcher was always available to answer any questions from participants pertaining to the study. All results and findings of the study are available and accessible to participants via the researcher.
CHAPTER FOUR

RESULTS

4.1 Introduction to results

All results from the study were analysed according to the General Linear Model: Repeated Measures, Mann-Whitney test (non-parametric test), Cross-tabulation, Fisher’s exact test and Regression analysis. Group C was determined to be the experimental group, who received the medication, *Coffea cruda* 200cH. Group P was determined to be the control group, who received the placebo.

4.2 Analysis according to Demographics

4.2.1 Age

Participants between the ages of 18 and 50 were recruited for this study.

![Figure 4.1 Graph depicting the age frequency of participants.](image)

*Figure 4.1* Graph depicting the age frequency of participants.
The highest frequency of participants fell between the ages of 20 and 40 years. The mean age of all 30 participants was determined to be between 32 and 33 years.

4.2.2 Age-Gender percent

Both male and female participants were recruited for this study.

Figure 4.2 Graph depicting percentage distribution of participants in relation to age and gender.

There was a fairly even distribution of females throughout the different age groups. It was determined that 43.5% of females fell between the ages of 49 to 50 years, whereas 71.4% of males fell between the ages of 26 to 35 years.
4.2.3 Gender frequency

Of participants who received the homoeopathic remedy (Code C), Coffea cruda 200cH, 66.7% were females and 33.3% were males. Code P indicates the control group who received the placebo.
4.2.4 Group frequency

The higher frequency of participants who received the homoeopathic remedy, *Coffea cruda* 200cH, fell in the age group between 26 to 35 years.

**Figure 4.4** Graph depicting percentage distribution of treatment among the different age groups.
4.3 Data obtained from Sleep Diary

All the results were obtained to determine the percentage of participants who had an improvement in their quality of sleep. The quality of sleep was assessed in terms of the duration of sleep, changes in sleep pattern, and satisfaction with sleep.

4.3.1 Duration of sleep
4.3.1.1 Experimental group: Group C

![Graph depicting mean number of hours slept in the experimental group (Group C).](image)

**Figure 4.5** Graph depicting mean number of hours slept in the experimental group (Group C).
In terms of the duration of sleep, Figure 4.5 indicates the mean number of hours sleep experienced by the experimental group (Group C). The y-axis represents the mean or average number of hours slept per individual. The x-axis represents the number of days over which the study was conducted. The average number of hours slept per night increased from 5.96 hours (357.6 minutes) on day 1 to 6.59 hours (395.4 minutes) on day 30. The average P-value for the overall duration of sleep experienced by the experimental group was P= 0.003. This was a statistically significant P-value.

4.3.1.2 Control group: Group P

Figure 4.6 Graph depicting mean number of hours slept in the control group (Group P).
In terms of the duration of sleep, Figure 4.6 indicates the mean number of hours sleep experienced by the control group (Group P). The y-axis represents the mean or average number of hours slept per individual. The x-axis represents the number of days over which the study was conducted. The average number of hours slept per night increased from 5.78 hours (346.8 minutes) on day 1 to 6.37 hours (382.2 minutes) on day 30. The average P-value for the overall duration of sleep experienced by the control group was P= 0.007. This was a statistically significant P-value for the control group, but less significant than the experimental group.

4.3.1.3 Experimental and control groups: Group C and Group P combined

Figure 4.7 Graph depicting the predicted number of hours slept for both the experimental and control groups.
Figure 4.7 is a Regression Analysis, which demonstrates the predicted number of hours slept between the experimental and control groups. The y-axis represents the mean or average number of hours slept per individual. The x-axis represents the number of days over which the study was conducted. The difference between the two lines is the effect of the medication. Both groups had an increase in the number of hours slept, although the experimental group increased more quickly than the control group. The mean number of hours slept between the two groups was determined to be between 6.287 hours (377.22 minutes) in the experimental group, and 6.053 hours (363.18 minutes) in the control group.

4.3.2 Satisfaction with sleep

4.3.2.1 Experimental group: Group C

Figure 4.8 Graph depicting sleep satisfaction in the experimental group (Group C).
Figure 4.8 represents the mean of sleep satisfaction rating per group versus the number of days over which the clinical trial was conducted. The above graph is a depiction of the participants’ satisfaction with their sleep throughout the 30-day trial period. Sleep satisfaction started improving from the beginning, then remained constant.

Sleep satisfaction in the experimental group = 2.609 + 0.007 Day. According to the best fitting line, the experimental group appears to have started with a higher sleep satisfaction in the early part of the experiment.

The average P-value for the overall satisfaction of sleep in the experimental group was P= 0.85. This indicated a change in sleep satisfaction, although this was not statistically significant.

4.3.2.2 Control group: Group P

![Graph depicting sleep satisfaction in the control group (Group P).](image)

Figure 4.9 Graph depicting sleep satisfaction in the control group (Group P).
Figure 4.9 represents the mean of sleep satisfaction rating per group versus the number of days over which the clinical trial was conducted. The above graph is a depiction of the participants’ satisfaction with their sleep throughout the 30-day trial period. According to the best fitting line, sleep satisfaction in the control group started off low, and improved thereafter.

Sleep satisfaction in the control group = 2.480 + 0.015 Day, thus indicating that sleep satisfaction started at 2.480 and improved by 0.015 per day.

The average P-value for the overall satisfaction of sleep was P= 0.002. This indicated a statistically significant change in sleep satisfaction in the control group.

4.3.3 Overall change in sleep pattern
4.3.3.1 Experimental group: Group C

Figure 4.10 Overall change in sleep pattern in the experimental group (Group C).
The above graph represents the percentage of participants in the experimental group who have experienced a change in sleep pattern versus the number of days over which the study was conducted.

Change in sleep pattern for the experimental group = 81.087 – 0.794 Day

The experimental group had greater changes in sleep pattern than the control group on days 6, 7, 8, 16, 19, 20, 21, 22, 24, 26 and 28.

The average P-value for the overall change in sleep pattern in the experimental group was P= 0.001. This indicated a statistically significant difference in overall change in sleep pattern in the experimental group.

Both, the experimental and control groups had equivalent changes in sleep pattern on days 10, 15, 17, and 25.

4.3.3.2 Control group: Group P

![Graph showing overall change in sleep pattern in the control group (Group P).](image)

**Figure 4.11** Overall change in sleep pattern in the control group (Group P).
The above graph represents the percentage of participants in the control group who have experienced a change in sleep pattern versus the number of days over which the study was conducted.

Change in sleep pattern for the control group = 68.410 – 0.17 Day

The experimental group had lesser changes in sleep pattern than the control group on days 1, 2, 3, 4, 5, 9, 11, 12, 13, 14, 18, 23, 27, 29, and 30.

The average P-value for the overall change in sleep pattern in the control group was P= 0.534. This indicated no significant difference in the change in sleep pattern in the control group.

4.3.4 Improved change in sleep pattern
4.3.4.1 Experimental group: Group C

Figure 4.12 Improved change in sleep pattern in the experimental group (Group C).
The above graph represents the number of participants in the experimental group who have experienced an improvement in their sleep pattern versus the number of days over which the study was conducted.

Improved change in sleep pattern for the experimental group = 19.745 + 0.798 Day

The experimental group had greater improvements in their sleep pattern than the control group on days 6, 7, 8, 9, 10, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24 and 29 of the clinical trial.

The average P-value for the improved change in sleep pattern in the experimental group was P= 0.002. This value indicates a statistically significant difference in the improved change in sleep pattern in the experimental group, and thus confirms a positive improvement in participants’ change in sleep pattern per day.

The experimental group’s improvement in sleep pattern was equivalent to the control group’s on days 1, 12, 26, 28 and 30.

Both, the experimental and control groups experienced no improvement in their change in sleep pattern on day 2.
4.3.4.2 Control group: Group P

![Graph showing improved change in sleep pattern in the control group (Group P).]

**Figure 4.13** Improved change in sleep pattern in the control group (Group P).

The above graph represents the number of participants in the control group who have experienced an improvement in their sleep pattern versus the number of days over which the study was conducted.

Improved change in sleep pattern for the control group = 11.895 + 0.546 Day

The control group had greater improvements in their sleep pattern than the experimental group on days 3, 4, 5, 11, 13, 25 and 27 of the clinical trial.

The average P-value for the improved change in sleep pattern in the control group was P = 0.011. This value indicates a statistically significant difference in the improved change in sleep pattern in the control group, and thus confirms a positive improvement in participants’ change in sleep pattern per day.
4.3.4.3 Experimental and control groups: Group C and Group P combined

Figure 4.14 Improved change in sleep pattern for both the experimental and control groups.

Figure 4.14 is a comparative graph representing the number of participants in both the experimental and control groups who have experienced an improvement in their sleep pattern versus the number of days over which the study was conducted.

The experimental group appears to have experienced a more constant improvement in their sleep pattern than the control group.
4.3.4.4 Non-parallel regression: Experimental and control groups combined

![Non-parallel regression graph](image)

*Figure 4.15* Non-parallel regression analysis graph depicting improved change in sleep pattern for the experimental and control groups combined.

4.3.4.5 Parallel regression: Experimental and control groups combined

![Parallel regression graph](image)

*Figure 4.16* Parallel regression analysis graph depicting improved change in sleep pattern for the experimental and control groups combined.
Figures 4.15 and 4.16 represent the percentage of participants who noticed an improvement in their sleep pattern versus the number of days over which the study was conducted.

After a regression analysis, figures 4.15 and 4.16 both display the linear relation between the percentage of participants who experienced an improvement in their sleep pattern per day.

Both groups had statistically significant results, but the experimental group improved faster and was better than the control group.
CHAPTER FIVE

DISCUSSION

All data were analysed from the initial questionnaire (Appendix B) and the patient sleep diary (Appendix C). Information from the follow-up questionnaire (Appendix D) could not be analysed statistically. The relevant information regarding participants’ sleep was obtainable from the sleep diary (Appendix C).

5.1 Demographic Results

5.1.1 Age

Participants between the ages of 18 and 50 were recruited for the study. As depicted in Figure 4.1, the age groups of participants was determined according to frequency. The mean age of participants was determined to be between 32 and 33 years.

5.1.2 Age-Gender percent

In this study, 23 participants were female and 7 were male. According to NAICS (2005), complaints of insomnia increase with age, and more women are affected with the condition. Zorick and Walsh (2000), state that women are 1.3 times more likely to report insomnia-like sleep problems than men are. With regard to age and gender, the demographic results of this study thus correlate to other findings of insomnia (NAICS, 2005), (Kupfer and Reynolds, 1997).
5.1.3 Gender frequency

As depicted earlier in Figure 4.3, 66.7% of participants who received the homoeopathic remedy, *Coffea cruda* 200cH, were females and 33.3% were males. Of participants who received the placebo, 86.7% were females and 13.3% were males.

5.1.4 Group frequency

A total of 30 participants between the ages of 18 and 50 years were randomly allocated into 1 of 2 groups of 15 each, Group C or Group P. Group C was determined to be the experimental group, who received the homoeopathic remedy *Coffea cruda* 200cH and Group P was determined to be the control group, who thus received the placebo.

Of the participants who received *Coffea cruda* 200cH, 46.7% were between 26 and 35 years of age. Furthermore, 40.0% of participants who received the placebo were between 18 and 25 years, whereas the other 40.0% of participants who received the placebo were between 36 and 49 years. According to figure 4.2, 43.5%, the highest frequency of female participants fell between the ages of 36 and 49 years. As mentioned earlier by NAICS (2005) and Kupfer and Reynolds (1997), complaints of insomnia increase with age and the condition is more common among women than men.

In this study, it was unfortunate that 40.0% of women in the older age group received the placebo, since insomnia is more prevalent among females in this and older age groups. This factor may have skewed the results. This may have been avoided if all 30 participants of this study were between 36 and 49 years of age. That would possibly help in contributing to an even distribution of the medication to women of the same age group.
5.2 Data obtained from Sleep Diary

5.2.1 Duration of sleep

The mean number of hours sleep experienced by the experimental group was calculated as follows:

Experimental group: Hours Sleep = 5.852 + 0.025 .Day [2.30]

Therefore, 0.025 hours (1.5 minutes) increase in sleep per day

In the experimental group, the average number of hours slept per night increased from 5.96 hours (357.6 minutes) on day 1 to 6.59 hours (395.4 minutes) on day 30. The experimental group thus had a total increase in sleep of 37.8 minutes over the 30 day clinical trial. The average P-value for the overall duration of sleep experienced by the experimental group was P= 0.003. This was a statistically significant P-value and, more significant than the control group.

The mean number of hours sleep experienced by the control group was calculated as follows:

Control group: Hours Sleep = 5.75 + 0.021 .Day

Therefore, 0.021 hours (1.26 minutes) increase in sleep per day

In the control group, the average number of hours slept per night increased from 5.78 hours (346.8 minutes) on day 1 to 6.37 hours (382.2 minutes) on day 30. The control group thus had a total increase in sleep of 35.4 minutes over the 30 day clinical trial. The average P-value for the overall duration of sleep experienced by the control group was P= 0.007. This was a statistically significant P-value, but less significant than the experimental group.

According to Joint Regression, the number of hours slept was statistically calculated as follows:

Hours sleep = 5.801 + 0.018 Day + 0.009. Group .Day

\[ 5.801 + (0.018 + 0.009) \text{ Day} \] for the experimental group

\[ 5.801 + (0.018 + 0.018) \text{ Day} \] for the control group
Thus, the total duration of time slept increased in the experimental group by 37.8 minutes. By the end of the clinical trial, both the experimental and control groups had an improvement in their duration of sleep, but the experimental group was sleeping better than the control.

According to the aims of this study, one of the parameters of assessing quality of sleep was monitoring the duration of sleep experienced by participants. It can thus be noted that even though the experimental and control groups both had statistically significant positive results, the experimental group outperformed the control group in terms of the duration of sleep.

**5.2.2 Satisfaction with sleep**

Sleep satisfaction in the experimental group = 2.609 + 0.007 Day
The average P-value for satisfaction of sleep in the experimental group was P= 0.85. From the above equation it can be mentioned that the experimental group did have a positive change in sleep satisfaction, but it was however, not statistically significant.

Sleep satisfaction in the control group = 2.480 + 0.015 Day
The average P-value for satisfaction of sleep in the control group was P= 0.002. From the above equation it can be mentioned that the control group did have a positive change in sleep satisfaction which was statistically significant.

Thus, the experimental and control groups both experienced a positive change in sleep satisfaction, although the control group had a statistically significant change. According to the best fitting line, the experimental group appears to have started with a higher sleep satisfaction in the early part of the experiment, thus not having much room for improvement. According to figures 4.8 and 4.9 there were wide fluctuations in satisfaction of sleep in the control group and less so in the experimental group.
The experimental group appeared to have a more constant pattern throughout the clinical trial.

It is possible that with regard to participants’ satisfaction with sleep, participants in the control group may have been experiencing the placebo effect. According to Ernst (2001), the placebo effect is regarded as the non-specific psychological or psychophysical therapeutic effect produced by the placebo. This effect may also be the result of spontaneous improvement attributed to the placebo.

According to Rajput and Bromley (1999), a sleep diary is beneficial in helping the individual to improve sleep hygiene. This could be another contributing factor to why the control group had an improvement in their sleep satisfaction.

5.2.3 Change in sleep pattern

Overall change in sleep pattern for the experimental group = 81.087 – 0.794 Day
The experimental group had greater overall changes in sleep pattern than the control group on days 6, 7, 8, 16, 19, 20, 21, 22, 24, 26 and 28.
The experimental group had a P-value of P= 0.001. This indicated a statistically significant difference in the overall change in sleep pattern in the experimental group, although the equation above does not confirm that this was a change for the better.

Overall change in sleep pattern for the control group = 68.410 – 0.17 Day
The control group had a P-value of P= 0.534. This indicated no significant difference in the overall change in sleep pattern in the control group.

After further statistical analysis, as noted below, it was possible to determine if participants experienced an improvement in their sleep pattern that was statistically significant or not.
Improved change in sleep pattern for the experimental group = 19.745 + 0.798 Day
The average P-value for the improved change in sleep pattern in the experimental group was P= 0.002. This value indicates a statistically significant difference in the improved change in sleep pattern in the experimental group. The above equation thus confirms a positive improvement in participants’ change in sleep pattern per day.

The experimental group had greater improvements in their sleep pattern than the control group on days 6, 7, 8, 9, 10, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24 and 29 of the clinical trial.

Improved change in sleep pattern for the control group = 11.895 + 0.546 Day
The average P-value for the improved change in sleep pattern in the control group was P= 0.011. This value indicates a statistically significant difference in the improved change in sleep pattern in the control group, and the above equation confirms a positive improvement in participants’ change in sleep pattern per day.

According to figure 4.14, the change in sleep pattern experienced by the control group was more erratic than that experienced by the experimental group. The control group did experience a change in sleep pattern, but as figures 4.15 and 4.16 display, the experimental group improved faster and was sleeping better than the control group.

The experimental group thus experienced a statistically significant improvement in their sleep pattern. The improvement in sleep pattern experienced by the control group was statistically significant, but was definitely outperformed by the experimental group. By the end of the clinical trial, the experimental group was sleeping better with less frequent interruptions.

According to Hering (1994), *Coffea cruda* is a homoeopathic remedy, which in a healthy individual will result in symptoms of insomnia, where the individual is unable to sleep due to an overactive mind. When the individual does eventually fall
asleep, it is a very restless sleep and the individual wakes at frequent intervals. Participants in this study were recruited on the basis that they experienced an inability to sleep due to an overactive mind. It can thus be mentioned that according to the similia principle, *Coffea cruda* 200cH had a positive effect on participants’ duration of sleep and sleep pattern.

5.3 Limitations of the study

In this study, 40.0% of women in the older age group received the placebo. Since insomnia is more prevalent among females in this and older age groups, results of the study could possibly have been more statistically relevant had these participants received *Coffea cruda* 200cH. This may have been avoided if all 30 participants of this study were matched and paired in terms of age and gender.

Participants of the study had to be suffering from insomnia for no longer than a year. It may prove effective if participants were paired according to the duration of which they had been suffering from insomnia.

Participants of this study were human subjects. Despite the fact that measures were taken to minimize as many variables as possible, the researcher was not in complete control of participant compliance in the study. Also, data was obtained from participants by means of a sleep diary, and no EEG recordings were taken. Information from a sleep diary is subjective, whereas that obtained from EEG monitoring is objective. Previous studies using *Coffea cruda* proved effective on rats possibly because EEG monitoring was used as a measure and could eliminate the aspect of participant compliance, thus removing as many variables from the study as possible.

A single dose of *Coffea cruda* 200cH was administered daily for 30 days to participants. This contradicts the law of the minimum dose. The results of the study
may have been more positive had participants been administered the remedy according to this law. Nevertheless, *Coffea cruda* 200cH was administered as a single remedy on the similia principle. According to the inclusion criteria, participants had to be suffering from insomnia due to nervous excitability. This matches the symptom picture of the remedy.

Participants in this study were requested to take the medication for the full duration of 30 days, irrespective of the changes they may have experienced in the interim. It is however possible that some of the participants could have started proving the remedy towards the end of the clinical trial. This may be taken into account where some participants experienced an improvement in their sleep by the middle of the trial and towards the end had a relapse of their old symptoms. Anecdotally, some participants were sleeping better once the study was over. It can thus be mentioned that participants only take the remedy for the duration that their symptoms persist. Once participants feel better, they may stop taking the remedy. Continuous intake of the homoeopathic remedy after the individual’s symptoms have improved may result in a homoeopathic proving of the remedy.

Coffee has a stimulating action on the central nervous system, resulting in insomnia and great nervous restlessness (Nash, 2003), (Vermeulen, 2002). It is thus possible that coffee intake at any point during the clinical trial may have affected participants’ arousal levels. As an oversight, it may have been beneficial if participants were taken off coffee completely for the duration of the clinical trial.
CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

*Coffea cruda* is a homoeopathic remedy, which, according to Gibson (1987), is commonly prescribed by homoeopathic clinicians in the treatment of insomnia. Some research using the homoeopathic remedy *Coffea cruda* has been conducted on rats. From these studies, *Coffea cruda* 30cH displayed an enhancement on NREM sleep. *Coffea cruda* 30cH also appeared to modify sleep pattern, which resulted in increased sleep intensity. *Coffea cruda* 200cH on the other hand, had an effect only on the synchronization of sleep. There is however still a need of conducting research using *Coffea cruda* in the treatment of insomnia on human subjects.

Statistical data proved that in terms of duration of sleep, both the experimental and control groups experienced a statistically significant improvement in their duration of sleep. However, the experimental group did eventually sleep better than the control group. By taking this fact into account, it can be concluded that *Coffea cruda* 200cH improved the duration of sleep.

With regard to a change in sleep pattern, the experimental group experienced a statistically significant improvement in their sleep pattern. The improvement in sleep pattern experienced by the control group was statistically significant, but was slightly outperformed by the experimental group. By the end of the clinical trial, the experimental group was sleeping better with less frequent interruptions.

Although both groups experienced positive changes in sleep satisfaction, these changes were not statistically significant for the experimental group. The changes
experienced by the control group were however significant. It is unclear why there was a greater sleep satisfaction among participants in the control group. A possible explanation is that *Coffea cruda* as a proving can cause irritability, and may have created an aggravation in the experimental group. Since a sleep diary is beneficial to improve sleep hygiene, this could be another contributing factor to why participants in the control group experienced an improvement in sleep satisfaction. A third explanation could be that participants in the control group may have been experiencing the placebo effect.

To conclude, in relation to the parameters of this study, both the experimental and control groups had statistically significant results. It is unclear why the control group behaved in the same way as the experimental group. The placebo effect and the use of a sleep diary are possible contributing factors. A longer trial is required to eliminate the placebo effect.

6.2 Recommendations

The following recommendations can be suggested for further research in this field:

- The sample size could be increased to prove beneficial for statistical purposes.

- Further research can be conducted on individuals in an age group older than 50 years, since insomnia is more prevalent among the elderly.

- Research on insomnia may also be conducted on elderly females only.

- It may prove beneficial to conduct a study on insomnia where participants are matched and paired in terms of age and gender.
• It could prove beneficial to explore the treatment of insomnia with the homoeopathic remedy *Coffea cruda* in different potencies, especially in a 30cH.

• Electroencephalogram (EEG) monitoring is also suggested as a means of measuring the depth of sleep experienced by the participant. This could aid statistical analysis along with the sleep diary.

• EEG monitoring at regular intervals on both the experimental and control groups may improve the objectivity of the study.

• By conducting further clinical trials on animal models, the placebo effect can be minimized.

• It may prove beneficial to conduct the clinical trial under laboratory conditions where participants can be monitored continually. This may improve participant compliance and reduce many variables.

• A follow up interview with participants at least 1 month after the clinical trial could prove beneficial in recording any improvement that may still occur in participants’ sleep, as the remedy may still be having an effect on insomnia.

• Similimum case studies which match the participant’s symptoms to an indicated remedy could prove beneficial since each individual may have characteristic symptoms requiring a different remedy for their insomnia. The similia principle would then be applied.
• A shorter clinical trial using *Coffea cruda* 200cH could be conducted to avoid the aspect of participants experiencing a marked aggravation, or even a proving.

• It may prove beneficial for participants to take the remedy in the morning on waking, instead of taking it just before going to bed.
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APPENDIX A

CONSENT FORM

A study to determine the efficacy of Coffea cruda 200cH on insomnia

Dear participant

You are invited you to participate in a study conducted by Mrs. Naseeha Kolia-Adam for a Masters degree in Homoeopathy. The purpose of the study is to determine the effect of Coffea cruda 200cH on insomnia.

Homoeopathy is a system of medicine, which has been founded by the German physician Dr Samuel Hahnemann (1755-1843). This form of medicine is based on the principle “Similia Similibus Curentur”, meaning, “like cures like”. Thus a medicine which is capable of producing certain effects when taken by a healthy human being, is capable of curing any illness that display similar effects. This is considered a safe and gentle form of treatment.

Coffea cruda is a homoeopathic remedy used to treat sleeplessness which occurs due to an over active mind and is considered very safe.

As a participant in this study you will be suffering from insomnia with a difficulty in falling asleep but should not be suffering from insomnia for more than one year and not be on any form of treatment for your insomnia.

There are two groups and you may fall into any one of the groups. One of the groups will receive Coffea cruda 200cH and the other group will receive the placebo. The placebo does not contain any medication. Neither you nor the researcher would know what medication you have received. The medication will be in liquid form and must
be taken orally. You will be requested to shake the bottle and then take 10 drops under your tongue 20 minutes before going to bed for 4 weeks. Within 30 minutes before taking the medication, you should not brush your teeth, eat or drink anything. With the medication, you will receive a sleep diary and you will be requested to complete it every morning. There will be a follow up visit at week 2 and week 4. You will be requested to bring along your sleep diary. The duration of the study will be 4 weeks.

There are no anticipated side effects in taking the medication. There is a possibility that the medication could cause a temporary worsening of your insomnia. In the event you experience any worrying symptoms, you are requested to 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 your 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 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 arise from the volunteers will be answered to the best of my ability.

Signature: __________________________        Date: _________________________

Mrs. Naseeha Kolia-Adam

Contact Details:
Supervisor:         Dr E.M. Solomon      Cell: 082 264 8862        Work: 011559-6262
Co- Supervisor:  Dr J Bond                   Cell: 082 333 1812

The Researcher:
Mrs. N Kolia-Adam                               Cell: 072 089 1188
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?

<table>
<thead>
<tr>
<th>Double bed with partner?</th>
<th>Single bed in same room with partner?</th>
<th>Alone?</th>
</tr>
</thead>
</table>

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?

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
</table>

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)

<table>
<thead>
<tr>
<th>Reason</th>
<th>Not a reason</th>
<th>Very Occasionally</th>
<th>Often</th>
<th>About every night</th>
</tr>
</thead>
<tbody>
<tr>
<td>Noises</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Going to the bathroom</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partners snoring</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thirst</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hunger</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nightmares</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mosquitoes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pets</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Children</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other, specify</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Activity</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caffeinated drinks (e.g. Coffee, tea)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoke cigarettes:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Watching TV:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reading:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Having Sexual intercourse:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Listen to music:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Listen to the radio:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drink milk or water:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other, specify:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If YES, how many glasses □
If YES, how many cups □
If YES, how many cigarettes □
If YES, how glasses □
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?

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walking in your sleep?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Talking in your sleep?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nightmares?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other, Specify?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

____________________________________________________

27) Are you taking any sleeping tablets?

| YES | NO |

28) If YES, please specify the type of tablet?

____________________________________________________

29) How many tablets are you taking? □

30) How often are you taking them? □

Drug history: _______________________________________

____________________________________________________

Medical history: _________________________________

____________________________________________________

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

## Patient Diary

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Time falling asleep</th>
<th>Satisfaction with Sleep (1-5)</th>
<th>What did you do/ have 1hr/s before bed?</th>
<th>No-of-Hours-Slept</th>
<th>Final time of waking</th>
<th>Have you noticed any change in sleep pattern?</th>
<th>Have you taken any medication to help you sleep?</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Reading</td>
<td></td>
<td></td>
<td>Yes/No, specify</td>
<td>Yes/No, specify</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Watching TV</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Having a bath</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Alcohol</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Caffeinated drinks</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Smoking</td>
<td></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Emotional upset</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sexual intercourse</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

**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?

<table>
<thead>
<tr>
<th>Having a difficulty waking up?</th>
<th>Unrefreshed?</th>
<th>Tired?</th>
<th>Alert?</th>
<th>Alert and Refreshed?</th>
</tr>
</thead>
</table>

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?

________________________
Appendix E: Advertisement

Tired

Do you have difficulty falling off to sleep? Are you between the ages of 18 and 40? Do you want to help yourself and others with this debilitating condition? If so..... YOU can be part of a supervised Homoeopathic Research Study... which offers free treatment.

For more information, Kindly contact:

Mrs. Naseeha Kolia-Adam on 072 089 1188
University of Johannesburg
Homoeopathic Clinic