

THE EFFICACY OF HOMOEOPATHIC SIMILLIMUM IN
THE TREATMENT OF CHRONIC PRIMARY INSOMNIA

By

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

I, Ashnie Maharaj, do declare that this mini dissertation is representative of my own work, both in conception and execution.

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ACKNOWLEDGEMENTS

I would like to express my immense gratitude to the following people:

- Dr Ingrid Couchman and Dr David Naude – I couldn't have asked for more patient, helpful or supportive supervisors. Thank you for your invaluable advice.
- My family – for their superb support and enormous encouragement.
- All lecturers at the Department of Homoeopathy, Durban Institute of Technology (DIT), especially Dr. Ashley Ross (H.O.D).
- Shami Harichand (former managing editor of Sunday Tribune).
- The staff at the Homoeopathic Day Clinic, DIT.
- All participants in the trial – without you this would not have been possible.
- Michelle Bakea (formerly co-director of the EEG and sleep lab at St. Augustine's Hospital, Durban). Thank you for believing in me and giving me a platform to speak about my study at the 5th Congress of the Sleep Society of South Africa.
- Dr Allison Bentley and Heidi Romain (Lecturers and Supervisors of Wits Dial-a-bed Sleep Laboratory- School of Physiology, University of the Witwatersrand, Faculty of Health Sciences, Medical School). You had faith in me when I had just a vague idea about conducting homoeopathic research into insomnia. Thank you for your consistent encouragement.

- The late Mr Mukesh Harilal. Thank you for volunteering to be my chauffeur when I needed to visit the Wits Dial-a-bed Sleep Laboratory.
- Dr Frida Rundell (psychologist and former HOD – Department of Child and Youth Development, DIT, Steve Biko Campus, Durban). Thanks for lending me your copy of the DSM IV TR when it couldn't be found on campus.
- Dr Katherine Peck and Dr. Brenda Sanders (Department of Homoeopathy, University of Witwatersrand, Doornfontein). Thank you for assisting me to find copies of other research done on insomnia.
- Dr Joanne Roohani (Homoeopath) Thank you for faxing all relevant information about your study. I hope that you decided to make an electronic copy for others to read.
- Dr Corrie Myburgh (Department of Chiropractic, DIT). Thank you for helping me make sense of qualitative and quantitative studies.
- And last, but far from least, Jerome – You have been my pillar of strength through all my hurdles. Thank you for your unconditional support and patience during my months of researching.

ABSTRACT

The purpose of this double-blind placebo controlled study was to evaluate the efficacy of homoeopathic simillimum in the treatment of chronic primary insomnia.

Chronic primary insomnia is defined as difficulty in initiating or maintaining sleep or of non-restorative sleep that lasts for at least 1 month and causes significant distress or impairment in social, occupational or other important areas of functioning (*Diagnostic and Statistical Manual of Mental Disorders*, 4th edition. Text revision. (DSM-IV TR), 2000: 599).

'Homoeopathy' comes from the words '*Homoeo*', meaning 'like' and '*Pathos*', meaning 'suffering'. The underlying concept of homoeopathy is that, in all conditions of disease, the human body is fully capable of healing itself by means of the vital force. It is a therapeutic method which clinically applies the Law of Similars (*similia similibus curentur*) and which uses medicinal substances in weak or infinitesimal doses. The homoeopathic simillimum is that remedy which most closely corresponds to the totality of symptoms. Simillimum treatment is based on a full evaluation of the patient's physical, emotional and mental characteristics (Swayne, 2000: 105).

Convenience sampling was utilized, whereby 30 participants were selected for the study on the basis of inclusion and exclusion criteria according to the DSM-IV TR (2000) diagnostic criteria for 307.42 primary insomnia. The participants were randomly divided between Treatment and Placebo Groups – 14 participants in the Treatment Group and 16 in the Placebo Group. This study was conducted at the Homoeopathic Day Clinic at the Durban Institute of Technology. The measurement tools utilized were a Sleep Diary (*Appendix A*), the Sleep Impairment Index (SII) (Morin, 1993: 199) (*Appendix B*) and the Dysfunctional Beliefs and Attitudes about Sleep Scale (DBAS) (Morin, 1993) (*Appendix C*).

The initial consultation consisted of an extensive homoeopathic interview and a full physical examination to exclude other disease conditions. There were 2 follow-up consultations at 2-week intervals. Homoeopathic medication was prescribed at the first and second consultations. The DBAS and SII were utilized at each consultation. The DBAS and SII used at the initial consult were baseline measurements. Each participant was instructed at the first consult to start a Sleep Diary. On completion of the trial the participants who received placebo were offered free treatment.

Due to the small sample size, non-parametric tests were conducted. The data accumulated from the Sleep Diary, SII and DBAS was evaluated and analysed statistically using the SPSS software (version 12.1).

Intra-group analysis (within each group) of Sleep Diary readings indicated a significant difference in the total hours of sleep in the Treatment Group between baseline and weeks 2, 3 and 4, as well as between weeks 2 and 4. There were no significant differences between any of the weeks in the Placebo Group.

The total hours of sleep in the Treatment Group at baseline (week 1) were 35 hours. There was a significant increase in total hours of sleep to 45 hours at week 2. The total hours of sleep in week 3 were 43 hours and at week 4 it stood at 41. The overall gain in hours slept was therefore 6 hours per week ($p = 0.002$). There were no significant differences between any of the weeks in the Placebo Group.

Inter-group analysis (between the groups) of Sleep Diary readings indicates that the degree of sleeplessness was comparable between the two groups at baseline. When comparing the net gains in hours slept and total hours of sleep per week between groups, it is noted that there were significant differences between the groups at all weeks. In the Treatment Group, total hours and net gains in hours slept were significantly different (higher) than those in the Placebo Group ($p=0.036$).

This positive trend was also reflected in the SII scores (both intra and inter-group analyses). Intra-group analysis of Sleep Impairment Index (SII) readings, comparing Follow-Up 1 and Follow-Up 2 as well as Follow-Up 2 and baseline,

revealed significant differences in all questions. Inter-group analysis of SII readings resulted in significant differences, within the first week of treatment, in 8 of the 11 questions. At the end of the trial the significant differences had increased to 10 of the 11 questions. However DBAS scores did not reflect this trend.

The results of this study lead to the conclusion that homoeopathic simillimum is more effective than placebo in the treatment of chronic primary insomnia, in terms of the Sleep Diary and SII. The study showed that homoeopathy can offer significant relief for insomniacs, when the simillimum is prescribed.

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DEFINITION OF TERMS

Aggravation

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

Allopathy

A term, loosely, and not always correctly, applied to the practice of mainstream (orthodox) medicine (Gaier, 1991: 30).

Amnesia

Lack (or loss) of memory. Inability to remember past experiences (Dorland's Illustrated Medical Dictionary, 1994: 60).

Anxiety

Anxiety is an unpleasant emotional state. It is often accompanied by physiological changes and behaviour similar to that caused by fear. As anxiety increases, performance efficiency increases proportionately, but only to an optimal level. Further increases in anxiety result in a decrease in performance efficiency (Beers and Berkow, 1999: 1512).

Anxiolytic

Reduces anxiety and exerts a calming effect with little or no effect on motor or mental functions. Used in acute anxiety states for its sedative and minor tranquilising capabilities (Shargel, Mutnick, Souney, Swanson and Block, 1997: 276).

Avogadro's number

Amedeo Avogadro (1776 – 1856) demonstrated that the number of molecules in one mole of any substance is 6.0255×10^{23} . Avogadro's number is of interest to homoeopathy because it specifies the potency at which a remedy does not contain any of the original material substance. (Swayne, 2000: 22).

Cataplexy

A condition in which there are abrupt attacks of muscular weakness and hypotonia triggered by an emotional stimulus such as mirth, anger, fear, or surprise. It is often associated with narcolepsy (Dorland's Illustrated Medical Dictionary, 1994: 276).

Centesimal potency

A dilution in the proportion of 1 part in 100 (Swayne, 2000: 35).

Chronic primary insomnia

Difficulty initiating or maintaining sleep or of non-restorative sleep that lasts for at least 1 month and causes significant distress or impairment in social, occupational or other important areas of functioning (Diagnostic and Statistical Manual of Mental Disorders, 2000: 599).

Circadian rhythm

Innate, daily fluctuations of behavioural and physiological functions. It is generally tied to the 24 hour day-night cycle. Sometimes it is tied to a different periodicity (e.g. 23 hour or 25 hour) when light or dark and other time cues are removed (Kryger, Roth and Dement, 1998).

Constitutional type

Classification according to which a particular medicine suits a specific kind of patient (Gaier, 1991: 103).

Drug tolerance

Progressive diminution of susceptibility to the effects of a drug. This results from its continued administration (Dorland's Illustrated Medical Dictionary, 1994: 1717).

Dyspnoea

This is the subjective sensation of shortness of breath, often exacerbated by exertion. It may be due to cardiac, lung or anatomical pathologies (Longmore, Wilkinson and Rajagopalan, 2004: 70).

Dyssomnia

A category of sleep disorders consisting of disturbances in the quality, amount or timing of sleep (Dorland's Illustrated Medical Dictionary, 1994: 519).

Homoeopathy

According to Gaier (1991:272), homoeopathy is a scientific system of medicinal therapy, founded by Samuel Hahnemann (1755-1843). It is based on the biological fact that a diseased organism can be restored to normal by specially-prepared medicinal stimuli. Homoeopathic medicines need only be administered in small doses, often in sub-physiological deconcentrations. This is due to an altered receptivity of tissue in disease to such stimuli, provided that

- a) The medicinal agents chosen would produce symptoms and clinical features (like those of the disease) in healthy organisms and
- b) Obstacles to cure have been removed

Homoeopathic drug preparation

According to Gaier (1991: 138), the three processes of homoeopathic drug preparation are:

1. Serial dilution
2. Succussion and
3. Trituration

Dilution reduces the toxicity of the original crude drug by serialized deconcentrations. Serial dilution means that each is prepared from the dilution that immediately came before it.

Succussion for soluble drugs, and trituration, for insoluble medicines, are the mechanical methods that impart the pharmacological message of the original substance (active principle) to the water molecules of the solvent or diluent respectively.

Hypnagogic imagery

Vivid sensory images occurring at sleep onset. It is a feature of narcolepsy (Kryger, Roth and Dement, 1998).

Hypnotic

Produces drowsiness and encourages the onset and maintenance of a state of sleep. It is often used in the treatment of sleep disorders (Shargel, et al. 1997).

Iatrogenic

Any adverse condition in a patient occurring as the result of treatment by a physician or surgeon, especially to infections acquired by the patient during the course of treatment (Dorland's Illustrated Medical Dictionary, 1994: 815).

Individualization

Is to particularize medicine for any one patient (Gaier, 1991: 283).

Infinitesimal dose

A dose of medicine whose source material has been diluted beyond Avogadro's number. It is unlikely to contain any molecules of the original active ingredient (Swayne, 2000: 112).

Insomnia

Refers to the inability to sleep or the experience of abnormal wakefulness (Dorland's Illustrated Medical Dictionary, 1994: 845).

Insomniac

An individual exhibiting insomnia (Dorland's Illustrated Medical Dictionary, 1994: 845).

LM Potency

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

Materia medica

A systematic documentation based on the knowledge of medicines. In homoeopathy, it implies the description of the nature and therapeutic repertoire of homoeopathic medicines; of the pathology, the symptoms and signs, the modifying factors and the general characteristics of the patient associated with them (Swayne, 2000: 132).

Menopause

Menopause marks the end of the menstrual cycle and ovulation, occurring naturally at an average age of fifty to fifty one years. Menopause is established when menses has not occurred for one year (Davidson, 1999: 597).

Nightmare

A terrifying dream; an anxiety attack during dreaming, accompanied by mild autonomic reactions (Dorland's Illustrated Medical Dictionary, 1994: 1138).

Pharmacology

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

Pharmacopoeia

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

Pharmacotherapy

The treatment of disease by medicines (Dorland's Illustrated Medical Dictionary, 1994: 1272).

Phenomenological

Any remarkable appearance: any sign or objective symptom (Dorland's Illustrated Medical Dictionary, 1994: 1275).

Placebo

Any dummy medical treatment; originally, a medicinal preparation having no specific pharmacological activity against the patient's illness or complaint given solely for the psycho-physiological effects of the treatment. Now also used in controlled studies to determine the efficacy of medicinal substances (Dorland's Illustrated Medical Dictionary, 1994: 1298).

Polysomnograph

A bio-medical instrument used for the measurement of multiple physiological variables of sleep (Kryger, Roth and Dement, 1998).

Potentization

According to Gaier (1991), it is imparting (along serial dilutions) the pharmacological message of the original substance (i.e. creating a template of the active principle) by means of trituration or succussion. It describes the process of modification of medicines as invented by Hahnemann.

It is characterized by the following features:

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

Primary

It is the first in order or in time of development (Dorland's Illustrated Medical Dictionary, 1994: 1351).

Qualitative analysis

The non-numerical examination and interpretation of observations for the purpose of discovering underlying meanings and patterns of relationships (Neuman, 1999: 418).

Qualitative research paradigm

It is a research approach, according to which research takes its departure point as the insider perspective on social action. Qualitative researchers attempt always to study human action from the insiders' perspective. The goal of research is defined as describing and understanding rather than the explanation and prediction of human behaviour. The emphasis is on methods of observation and analysis which include unstructured interviewing, participant observation and the use of personal documents (Mouton, 2001).

Quantitative analysis

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

Quantitative research paradigm

The quantitative researcher believes that the best or only way of measuring the properties of phenomena (e.g. the attitudes of individuals towards certain topics) is through quantitative measurement, which involves assigning numbers to the perceived qualities of things. Emphasis is placed on variables in describing and analysing human behaviour. Quantitative research plays a central role in controlling sources of error in the research process. The nature of the control is either through experimental control or through statistical controls (Mouton, 2001).

Simillimum

Is the single homoeopathic medicine, the drug picture of which most nearly approaches the total symptom complex of the patient (Gaier, 1991: 509).

Sleep latency

This is the time measured from “lights out,” or bed time, to the beginning of sleep (Kryger, Roth and Dement, 1998).

Sleep spindle

Episodically appearing, spindle shaped aggregate of 12 -14 Hz waves with a duration of 0.5 – 1.5 seconds. It is a phenomena found on the electroencephalogram readings of non-REM stage 2 sleep (Kryger, Roth and Dement, 1998).

Succussion

The action of shaking up, or the condition of being shaken up, vigorously of a liquid dilution of a homoeopathic medicine in its vial or bottle, where each stroke ends with a jolt, usually pounding the hand engaged in the shaking action against the other palm (Gaier, 1991: 352).

Susceptibility

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

Tachycardia

Rapid heart rate, usually defined by a pulse rate over 100 beats per minute (Kryger, Roth and Dement, 1998).

Thyrotoxicosis

A pathology of the thyroid gland where there are increased blood levels of triiodothyronin (T3) and thyroxine (T4) accompanied by decreased levels of thyroid stimulating hormone (TSH). Some signs and symptoms include loss of weight, an increase in appetite, psychosis, warm peripheries, goitre (a visibly enlarged thyroid gland seen as a mass in the neck) and bulging eyes (Longmore, Wilkinson and Rajagopalan, 2004: 304).

Trituration

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

CHAPTER 1

1.1 INTRODUCTION

Chronic primary insomnia is defined as difficulty initiating or maintaining sleep or of non-restorative sleep that lasts for at least 1 month and causes significant distress in areas of functioning (Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV TR), 2000: 599).

According to Ancoli-Israel and Roth (1999), chronic insomnia is a prevalent and distressing problem, reported to affect approximately 9% -10% of the population in the United States. Chronic insomnia, if untreated, can have social, economic and occupational impacts on the individual, as they are not functioning at their optimum (Morin, 1993: 9).

There are many side effects of allopathic drugs used to treat insomnia including nausea, vomiting, addiction and drowsiness (Beers and Berkow, 1999:1411-1412). Many people are becoming dissatisfied with allopathic medicine and are exploring alternative options. Therefore, questions about other treatment modalities should be examined (Roth, Roehrs, Costa e Silva and Chase, 1999).

Homoeopathy, based on the 'law of similars' is a system of medical therapeutics that subscribes to fundamental laws of nature. This allows homoeopathic remedies to utilise and enhance the body's curative powers. Homoeopathy is a

curative system of medicine as it restores the patient to health and balance, both mentally and physically (Eizayaga, 1991: 11, 37).

Homoeopathy is considerably cheaper than conventional medicine, making it a desirable alternative to allopathic medication (Ullman, 1991: 49).

1.2 PROBLEM STATEMENT

The purpose of this double-blind placebo-controlled study was to evaluate the efficacy of a homoeopathic simillimum in the treatment of chronic primary insomnia in terms of the patient's perception of the treatment using a Sleep Diary (*Appendix A*), the Sleep Impairment Index (SII) (Morin, 1993: 199) (*Appendix B*) and the Dysfunctional Beliefs and Attitudes about Sleep Scale (DBAS) (Morin, 1993: 201-204) (*Appendix C*).

1.3 ASSUMPTIONS

- Participants took the medication as prescribed.
- Participants adhered to instructions to abstain from any other insomnia treatment for the duration of the study.

1.4 HYPOTHESES

It is hypothesised that simillimum will have a significant impact on chronic primary insomnia in terms of the findings of the Sleep Diary (*Appendix A*), Sleep Impairment Index (SII) (Morin, 1993: 199) (*Appendix B*) and the Dysfunctional Beliefs and Attitudes about Sleep Scale (DBAS) (Morin, 1993: 201-204) (*Appendix C*).

It is hypothesised that simillimum will have a more significant impact on chronic primary insomnia compared to placebo in terms of the three measurement tools completed during the study.

For the above two hypotheses, the null hypothesis states that there is no significant differences between the relevant variables. The alternate hypothesis states that there will be a significant difference between the variables according to the three measurement tools.

CHAPTER 2

REVIEW OF RELATED LITERATURE

2.1 INTRODUCTION

Insomnia is the most commonly reported sleep problem in industrialized nations worldwide, leading to emotional distress, daytime fatigue and loss of productivity. The enormity of this problem indicates that routine clinical assessment and treatment of insomniacs may have important health consequences for the patient (Sateia, Doghramji, Hauri, and Morin, 2000).

Insomnia is an epidemic of silent sufferers. Estimates of the economic costs of insomnia vary, illustrating the difficulty in assessing its consequences. With all of its associated health and quality-of-life issues, risk of accidents and morbidity, insomnia is justifiably considered an important public health problem (Christer and Markuu, 2002).

The purpose of this double-blind-placebo-controlled study was to evaluate the efficacy of homoeopathic simillimum in the treatment of chronic primary insomnia in terms of the patient's perception of the treatment, using a Sleep Diary (*Appendix A*), the Sleep Impairment Index (SII) (Morin, 1993: 199) (*Appendix B*) and the Dysfunctional Beliefs and Attitudes about Sleep Scale (DBAS) (Morin,

1993: 201-204) (*Appendix C*). Consultations were conducted at the Homoeopathy Day Clinic, at the Durban Institute of Technology.

Homoeopathy is an approach that utilizes medicines that stimulate the body's own immune and defence systems to initiate the healing process. It is an approach that individualizes medicines according to the totality of the person's physical, emotional and mental symptoms (Ullman, 1991: 3).

2.2 SLEEP PHYSIOLOGY

Sleep is defined as unconsciousness from which the person can be aroused by sensory or other stimuli (Guyton and Hall, 1997: 488).

Sleep comprises two distinct physiological states: non-rapid eye movement (NREM) sleep and rapid eye movement (REM) sleep. These two states of sleep are characterised by varying brain wave activity. People normally cycle through four stages of NREM sleep, usually followed by a brief interval of REM sleep, 5 to 6 times every night (Haslett, Chilvers, Hunter and Boon, 1999: 1093) (see Figure 2.1).

Stages of the Sleep Cycle

People normally cycle through distinct stages of sleep 5 or 6 times during the night. Relatively little time is spent in deep sleep (stages 3 and 4). More time is spent in rapid eye movement (REM) sleep as the night progresses, but this stage is interrupted by brief returns to light sleep stage 1). Brief awakenings occur throughout the night.

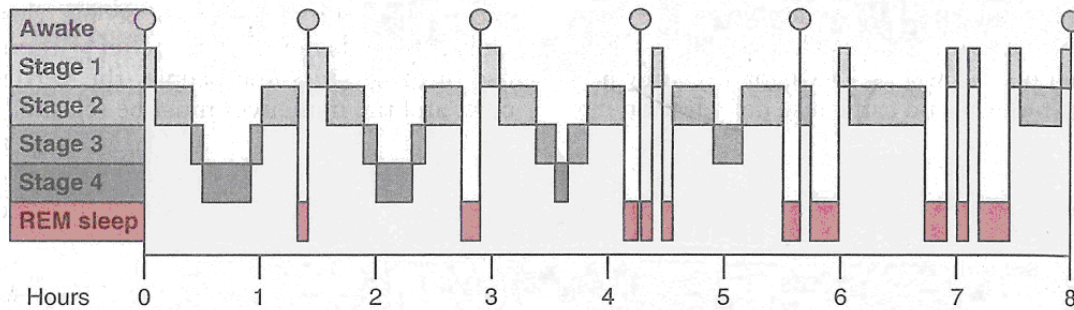


Figure 2.1 The stages of the sleep cycle (Beers, Fletcher, Jones, Porter, Berkwits and Kaplan, 2003: 468)

2.2.1 NREM SLEEP

NREM sleep consists of four stages:

- **Stage 1** is characterized by a decrease in brain wave activity, which is characteristic of relaxed wakefulness with the eyes closed. There is slow rolling of the eyes and the electromyogram (EMG) activity is low to moderate, which is comparable to a “drowsy” state. This is a transition from wakefulness to sleep and occupies about 5% of time spent asleep in healthy adults (Guyton and Hall, 1997: 489).

- In **stage 2** eye movements becomes rare and EMG is still low to moderate. Stage 2 is considered to be the first true stage of sleep due to the presence of “sleep spindles.” This occupies about 50% of time spent asleep (Kryger, Roth and Dement, 1998: 16).
- **Stages 3 and 4** are known as ‘slow wave’ sleep because they are associated with low-frequency, synchronised waves on the electroencephalogram (EEG). This is the deepest level of sleep and occupies about 10% - 20% of sleep time. This sleep is exceedingly restful and is associated with a decrease in peripheral vascular tone. There is also a decrease in blood pressure, respiratory rate, and basal metabolic rate (Guyton and Hall, 1997: 489).

2.2.2 REM SLEEP

According to Guyton and Hall (1997), REM sleep develops after progression through the various stages of NREM sleep. In a normal night of sleep, bouts of REM sleep, lasting 5 to 30 minutes, usually appear on the average every 90 minutes.

Characteristics of REM sleep are:

- An association with active dreaming. Dreams during REM sleep are remembered, whereas those of slow wave sleep are usually not.
- The heart and respiration rates usually become irregular, which is characteristic of the dream state.
- A few irregular muscle movements which occur despite the inhibition of peripheral muscles.
- The brain is highly active in REM sleep, and the overall brain metabolism may be increased as much as 20%.

Sleep onset, under normal circumstances in healthy adults, is through NREM sleep. This fundamental principle reflects a highly reliable finding and is important in considering normal versus pathological sleep (Kryger, Roth and Dement, 1998: 17).

2.3 CLASSIFICATION OF SLEEP DISORDERS

According to DSM-IV TR (2000: 597 - 630), sleep disorders are classified into four major sections according to their aetiology:

- Primary sleep disorders,
- Sleep disorder related to a general medical condition,
- Sleep disorder related to another mental disorder and
- Substance induced sleep disorder.

Primary sleep disorders are subdivided into:

- Dyssomnias. This section includes:
 - Primary insomnia
 - Primary hypersomnia
 - Narcolepsy
 - Breathing-related sleep disorder
 - Circadian rhythm sleep disorder and
 - Dyssomnia not otherwise specified
- Parasomnias. This section includes:
 - Nightmare disorder
 - Sleep terror disorder
 - Sleepwalking disorder and
 - Parasomnia not otherwise specified

Figure 2.2 is a summary of the classification of sleep disorders.

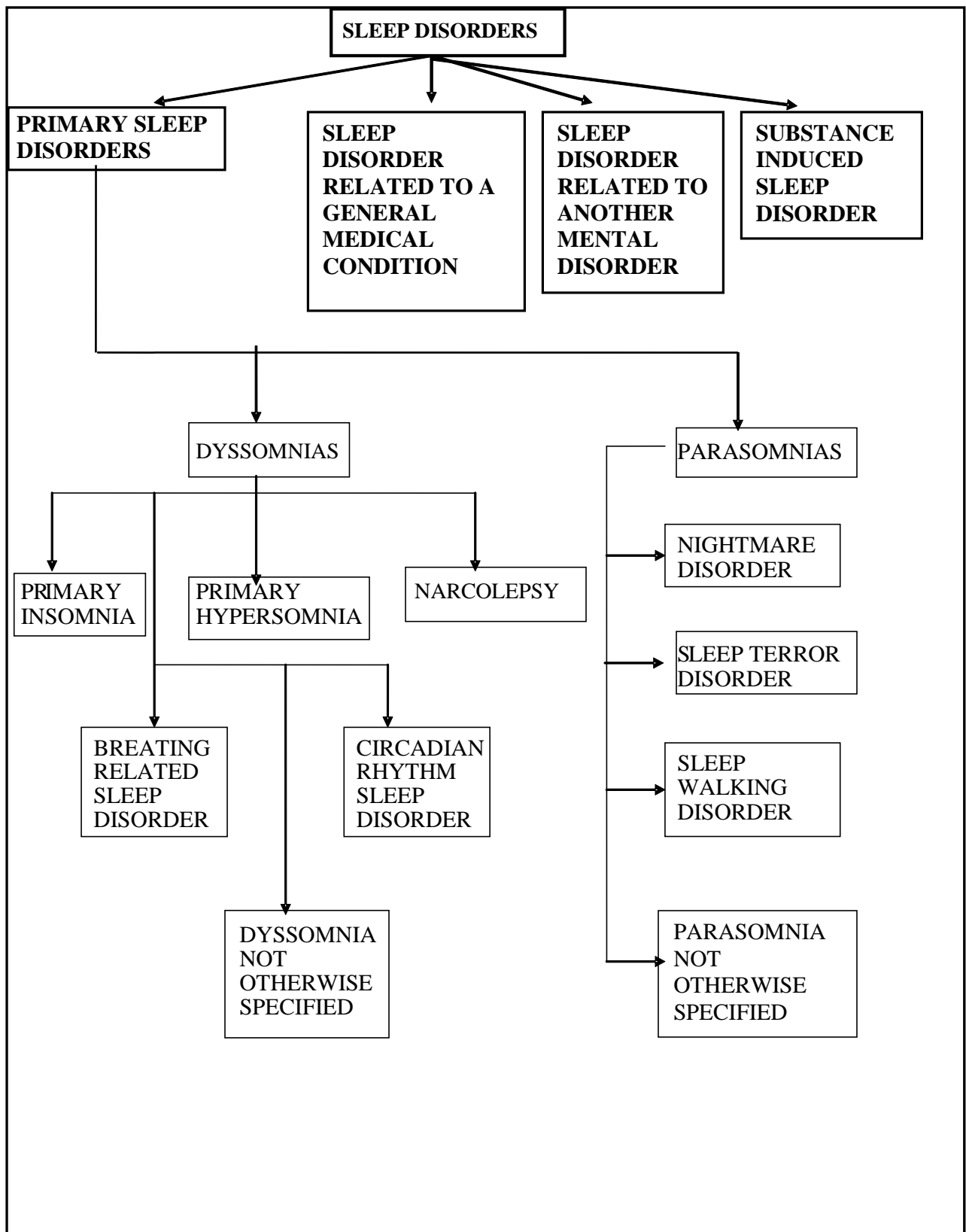


Figure 2.2 Summary: Classification of sleep disorders (DSM-IV TR, 2000:

597 - 630)

2.3.1 PRIMARY SLEEP DISORDERS

Primary sleep disorders are presumably due to an abnormality in sleep-wake generating or timing mechanisms. They are not due to another mental disorder, a general medical condition, or a substance. Primary sleep disorders are subdivided into:

2.3.1.1 Dyssomnias

Dyssomnias are characterized by abnormalities in the amount, quality or timing of sleep. They are primary disorders of initiating or maintaining sleep or of excessive sleepiness. This section includes:

2.3.1.1.1 Primary Insomnia

The essential feature of primary insomnia is a complaint of difficulty initiating or maintaining sleep or of nonrestorative sleep that lasts for at least 1 month and causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.

2.3.1.1.2 Primary Hypersomnia

The essential feature of primary hypersomnia is excessive sleepiness for at least 1 month, where there are prolonged sleep episodes or daytime sleep episodes that occur almost daily.

2.3.1.1.3 Narcolepsy

The essential features of narcolepsy are

- repeated irresistible attacks of refreshing sleep,
- cataplexy (i.e., brief episodes of sudden bilateral loss of muscle tone, most often in association with intense emotion) and
- recurrent intrusions of REM sleep into the transition period between sleep and wakefulness.

The individual's sleepiness decreases after a sleep attack, only to return hours later. The sleep attacks must occur daily over a period of at least 3 months to make a diagnosis of narcolepsy.

2.3.1.1.4 Breathing-Related Sleep Disorder

The essential feature is sleep disruption, leading to excessive sleepiness or insomnia that is due to a sleep-related breathing condition (e.g., obstructive or central sleep apnoea syndrome or central alveolar hypoventilation syndrome).

2.3.1.1.5 Circadian Rhythm Sleep Disorder

The essential feature of circadian rhythm sleep disorder is a persistent or recurrent pattern of sleep disruption leading to excessive sleepiness or insomnia. This is due to a mismatch between the sleep-wake schedule required by a person's environment and his or her circadian sleep-wake pattern.

2.3.1.1.6 Dyssomnia Not Otherwise Specified

This category is for insomnias, hypersomnias or circadian rhythm disturbances that do not meet criteria for any specific dyssomnia.

2.3.1.2 Parasomnias

Parasomnias are characterized by abnormal behavioural or physiological events occurring in association with sleep. Parasomnias represent the activation of physiological systems at inappropriate times during the sleep-wake cycle. These disorders involve activation of the autonomic nervous system, motor system, or cognitive processes during sleep or sleep-wake transitions. Individuals with parasomnias usually present with complaints of unusual behaviour during sleep, rather than complaints of insomnia or excessive daytime sleepiness. This section includes:

2.3.1.2.1 Nightmare Disorder

The essential feature of nightmare disorder is repeated awakenings from the major sleep periods or naps with detailed recall of extremely frightening dreams (usually involving threats to survival, security, or self-esteem). The awakenings generally occur during the second half of the sleep period. On awakening from the frightening dreams, the person rapidly becomes oriented and alert (in contrast to the confusion and disorientation seen in sleep terror disorder and some forms of epilepsy.)

2.3.1.2.2 Sleep Terror Disorder

The essential feature of sleep terror disorder is recurrent episodes of abrupt awakening from sleep, usually occurring during the first third of the major sleep episode, and beginning with a panicky scream. There is intense fear and signs of autonomic arousal, such as tachycardia, rapid breathing, and sweating, during each episode.

2.3.1.2.3 Sleepwalking Disorder

The essential feature of sleepwalking disorder is repeated episodes of rising from bed during sleep and walking about, usually occurring during the first third of the major sleep episode. While sleepwalking, the person has a blank, staring face, is relatively unresponsive to the efforts of others to communicate with him or her, and can be awakened only with great difficulty. On awakening (either from the sleepwalking episode or the next morning), the person has amnesia for the episode.

2.3.1.2.4. Parasomnia Not Otherwise Specified

This category is for disturbances that are characterised by abnormal behavioural or physiological events during sleep or sleep-wake transitions, but that do not meet criteria for a more specific parasomnia.

2.3.2 SLEEP DISORDER RELATED TO ANOTHER MENTAL DISORDER

This group of sleep disorders involves sleep disturbance resulting from a diagnosed mental disorder (often mood disorder or anxiety disorder). It is presumed that the pathophysiological mechanisms responsible for the mental disorder have an effect on sleep-wake regulation.

2.3.3 SLEEP DISORDER DUE TO A GENERAL MEDICAL CONDITION

This involves sleep disturbances resulting from the direct physiological effects of a general medical condition.

2.3.4 SUBSTANCE-INDUCED SLEEP DISORDER

This involves sleep disturbances resulting from concurrent use of a substance (including medications). It may also be a result of recent discontinuation of use of a substance.

2.4 PATHOPHYSIOLOGY OF INSOMNIA

Insomnia is defined as a complaint of perceived poor sleep quality, which results in the impairment of daytime function. It is a perception by patients that their sleep is inadequate or abnormal. Symptoms include difficulty initiating sleep, frequent awakenings from sleep, a short sleep time, and non-restorative sleep (Kryger, Roth and Dement, 1998: 483).

The severity of insomnia often depends on the frequency and duration of the sleep problem. Virtually everyone encounters situational sleep disturbances, and as such would not necessarily be considered an insomniac. Sleep difficulties must be experienced three or more nights per week to be clinically significant (Morin, 1994).

According to the International Classification of Sleep Disorders, insomnia lasting less than 1 month is considered transient, and it generally resolves itself after an adjustment to stressful events is made. Insomnia lasting between 1 and 6 months is considered sub acute, and when it persists for longer than 6 months it is classified as chronic (Morin, 1994).

According to Beers and Berkow (1999: 1410), Primary insomnia may be longstanding, with little relationship to immediate somatic or psychic events. Insomnia may be secondary to emotional problems, pain, physical disorders or use or withdrawal of drugs.

According to Morin (1993: 3), insomnia encompasses a wide variety of complaints typically reflecting unsatisfactory duration, efficiency or quality of sleep.

Presenting complaints include:

- problems with falling asleep at bedtime (sleep-onset insomnia),
- waking up in the middle of the night, with difficulty in going back to sleep (sleep-maintenance insomnia) ,
- awakening too early in the morning (terminal insomnia)

These difficulties are not exclusive, as a person may present with one, two or all three problems. Sleep-onset insomnia requires that the latency to sleep onset after turning the lights out be greater than 30 minutes (Morin, 1993: 3).

Sleep-maintenance insomnia involves either frequent and/or extended nocturnal awakening totalling more than 30 minutes of wakefulness after sleep onset, or premature awakening in the morning with less than 6.5 hours of sleep (Morin, 1993: 4).

Terminal insomnia involves a short time spent asleep resulting in non-restorative sleep. People suffering from terminal insomnia usually awaken too early in the morning. This may occur with or without sleep-onset insomnia and/or sleep maintenance insomnia. It is usually transient and can occur in individuals who in general sleep normally. Terminal insomnia may be related to the environment in which the individual sleeps or to the experience of psychological stress (Kryger, Roth, and Dement, 1998; 486).

Sleep may be perceived as qualitatively deficient. Some people describe their phenomenological experience of a poor quality of sleep, as that of being in a “twilight zone” (half awake, half asleep) all night long. There is no major problem with initiating or maintaining sleep, however, its quality is described as non-restorative, with persistent thoughts preventing the natural progression to a deep sleep. This is associated with “alpha-delta” sleep, where there is frequent intrusion of alpha rhythms (wakefulness) into non-rapid-eye-movement sleep stages (Morin, 1993: 4).

Because sleep patterns change as people age, the elderly may think they have insomnia, when they do not. As people age, they tend to sleep less at night and nap during the day. Stage 4 sleep becomes shorter and eventually disappears (Beers, et al. 2003: 468).

2.5 DIAGNOSTIC CRITERIA OF PRIMARY INSOMNIA

According to the DSM-IV TR (2000: 604), the diagnostic criteria for 307.42

Primary Insomnia are:

- A. The predominant complaint is difficulty initiating or maintaining sleep, or
- B. Nonrestorative sleep, for at least 1 month.
- C. The sleep disturbance (or associated daytime fatigue) causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.
- D. The sleep disturbance does not occur exclusively during the course of narcolepsy, a breathing-related sleep disorder, circadian rhythm sleep disorder, or a parasomnia.
- E. The disturbance does not occur exclusively during the course of another mental disorder (e.g. major depressive disorder, generalised anxiety disorder, a delirium).
- F. The disturbance is not due to the direct physiological effects of a substance (e.g. a drug of abuse, a medication) or a general medical condition.

2.6 AETIOLOGY OF PRIMARY INSOMNIA

Many cases of insomnia have a fairly sudden onset at a time of psychological, social, or medical stress. Primary insomnia often persists long after the original causative factors resolve. It is associated with increased physiological, cognitive, or emotional arousal during the night together with negative conditioning for sleep (Kryger, Roth and Dement, 1998: 483).

Several predisposing factors to insomnia have been hypothesized, including a familial component. Yves, Morin, Cervera, Carlander, Besset and Billiard (2003) found that more than one third of insomniacs had a familial history. Their study reported a dramatic increase of familial aggregation of insomnia, warranting further genetic studies in primary insomnia with early age onset.

Many insomniacs have a history of easily disturbed sleep before the development of persistent sleep difficulties. Other factors that may contribute include anxious over-concern with general health and increased sensitivity to the daytime consequences of sleep loss. Symptoms of anxiety or depression that do not meet criteria for a specific mental disorder may be present (Sateia, et al. 2000).

2.7 EPIDEMIOLOGY OF PRIMARY INSOMNIA

Insomnia is a widespread problem affecting essentially everyone at one period or another. It is the most common of all sleep disorders, and perhaps the most frequent health complaint after pain. Insomnia is associated with demographic variables, including age, gender, occupational and socioeconomic status (Smith and Trinder, 2001).

Complaints of insomnia are more prevalent with increasing age and among women. This may indicate an increased willingness among women to acknowledge this complaint. Insomnia is more common among homemakers, the unemployed, separated or widowed individuals, and those living alone. This is inversely related to educational and socioeconomic levels, though this finding is not consistent across surveys. Insomnia is certainly not restricted to people of lower socioeconomic levels. Many wealthy and highly successful individuals are insomniacs, although they may be less inclined to acknowledge it, for it may be perceived as a sign of weakness (Morin, 1993: 6).

Primary insomnia typically begins in young adulthood or middle age and is rare in childhood or adolescence. Young adults complain of difficulty initiating sleep, whereas midlife and elderly adults are more likely to complain of difficulty maintaining sleep and early morning awakening (Smith and Trinder, 2001).

In clinics specializing in sleep disorders, approximately 15% - 25% of individuals are diagnosed with primary insomnia (DSM-IV TR, 2000: 601).

2.8 IMPACT OF CHRONIC INSOMNIA

The extent to which psychological, social, and occupational functioning are affected by chronic insomnia is one of the most important criteria, when determining its clinical significance. Sleep disturbances can adversely affect a person's life, causing significant psychosocial, occupational and health repercussions. Chronic insomnia may lead to decreased feelings of well being during the day. Prolonged sleep disturbances that characterize primary insomnia constitute a risk factor for the development of subsequent mood disorders and anxiety disorders (Morin, 1993: 9, 14).

Analyses suggest that chronic insomnia is a “daytime” disorder as well as a “night-time” one (Grunstein, 2002). According to Moul, Nofzinger, Pilkonis, Houck, Miewald, and Buysse (2002), insomnia patients frequently report daytime symptoms. These include:

- decreased alertness
- being unrefreshed
- sleepiness
- inability to nap
- irritability

- tension
- hyperarousal
- depressed mood
- impaired memory functioning
- decreased memory and concentration
- social aversion
- anergia (extreme fatigue and lack of energy)
- disabilities in work and social life and
- pervasive malaise which affects many aspects of daytime functioning

Insomnia occurs with few physical signs, and is defined largely on the basis of the patient's self report. Individuals with primary insomnia may appear fatigued or haggard, but show no other characteristic abnormalities on physical examination. There may be an increased incidence of stress-related psychophysiological problems such as tension headaches, increased muscle tension and gastric distress (Sateia, et al. 2000).

2.9 TREATMENT FOR PRIMARY INSOMNIA

2.9.1 PHARMACOTHERAPY

Pharmacotherapy is the most frequently used method for treating insomnia; however, this may lead to iatrogenic insomnia. According to Morin (1993), chronic use of sleep medications undermines the development of self-management skills to cope with insomnia.

Insomnia sufferers seek treatments for insomnia mainly because of perceived distress or impairment rather than how much sleep they get. The 1991 National Sleep Foundation survey found that 46% of patients with chronic insomnia discussed their sleep disturbances with a physician. The survey revealed that to promote sleep, 23% of people used over-the-counter medications; 28% used alcohol; and 21% used prescribed medications. Amongst the sleep-promoting agents, 61% received hypnotics, 27% anxiolytics and 11% antidepressants.

People with primary insomnia sometimes use medications inappropriately: hypnotics or alcohol to help with night-time sleep, anxiolytics to combat tension or anxiety, and caffeine or other stimulants to combat excessive fatigue. Chronic insomnia may induce emotional distress and increase the risk of substance abuse or substance dependence (Christer and Markuu, 2002).

Intermittent use of hypnotics and anxiolytics is needed to prevent tolerance. However this intermittent schedule is powerful in creating and perpetuating a vicious cycle - insomnia, medication intake, tolerance, cessation of medication, rebound insomnia and resumption of medication (see Figure 2.3) (Morin, 1993: 164).

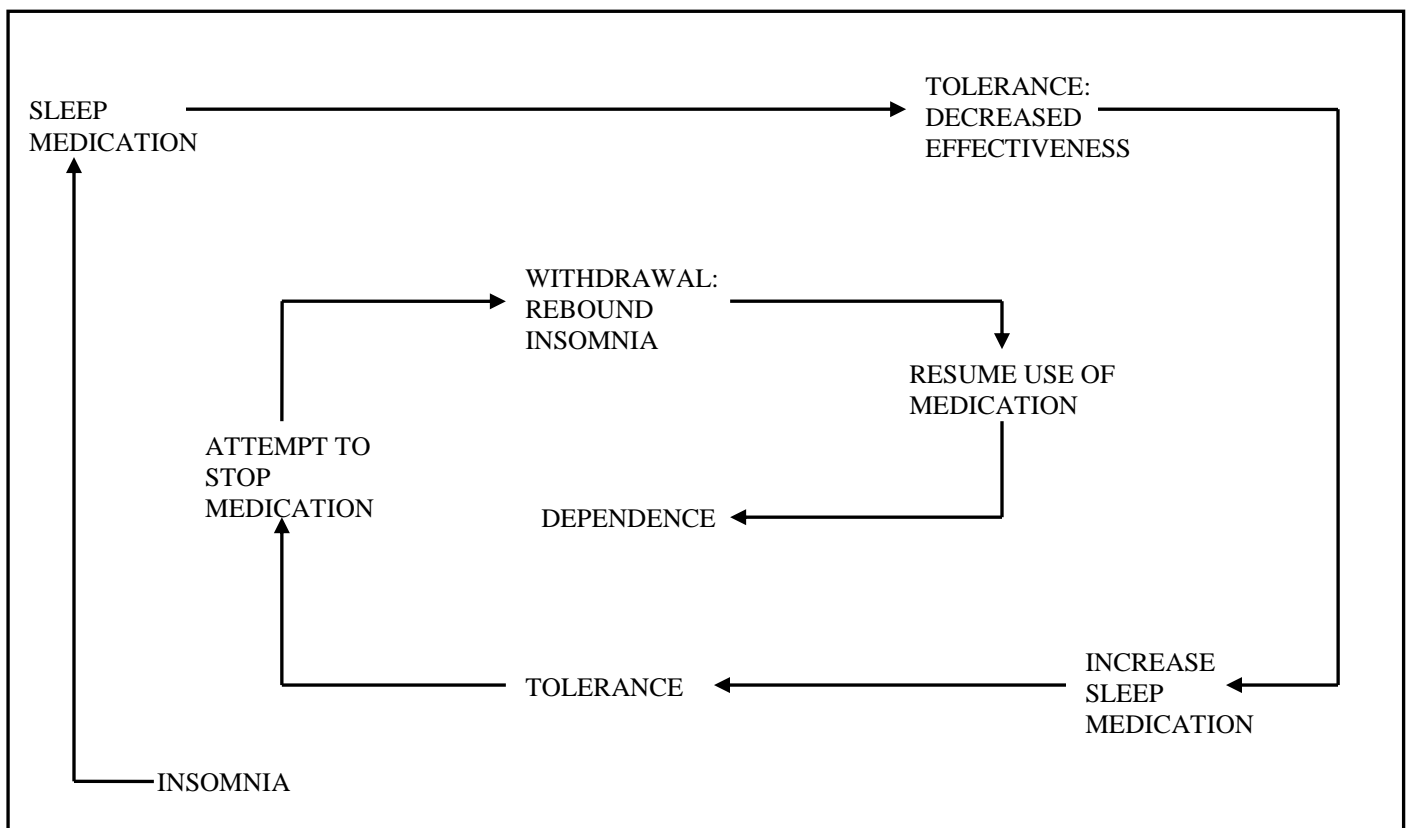


Figure 2.3 The cycle of drug-dependent insomnia (Morin, 1993: 164)

2.9.1.1 Hypnotics

Hypnotic drugs are often required for insomnia due to emotional disturbances (other than depression), especially if the patient's sense of well-being is impaired.

Patients are advised to use hypnotics for a short term (2 – 4 weeks) or episodically. Adverse effects of excessive hypnotics intake include tolerance, addiction, drowsiness, lethargy, hangover and amnesia. Often, skin eruptions and gastric-intestinal disturbances such as nausea and vomiting, are common side effects. In the elderly, any hypnotic can cause restlessness, excitement or exacerbations of delirium and dementia. Sudden withdrawal after prolonged use may lead to severe tremors or seizures (Beers and Berkow, 1999: 1411-1412).

The benzodiazepines (BZDs) and benzodiazepine-like hypnotics are considered the drugs of choice for symptomatic relief of insomnia due to their safety and effectiveness. However, larger doses of benzodiazepines may induce serious respiratory depression. Even short acting BZDs may impair psychomotor performance and memory the next day. Some patients report an increase in daytime anxiety after repeated use or withdrawal (Beers and Berkow, 1999: 1413).

2.9.1.2 Antidepressants

Tricyclic antidepressants are considered a better choice than benzodiazepines, especially among patients with a suicidal tendency. There is an increasing trend among physicians to prescribe anti-depressant medications for treating insomnia even in non-depressed people. Due to their sedative properties, some antidepressants are prescribed in sub therapeutic dosage. The potential for abuse and physical dependency is lower. However, there is a higher potential for drug interaction (Morin, 1993: 159).

According to Shargel, et al. 1997, tricyclic antidepressants can cause adverse effects including:

- Central nervous system effects such as drowsiness, dizziness, weakness, fatigue and confusion
- Cardiovascular effects, such as tachycardia and interference with the conduction system of the heart
- Gastro-intestinal effects, such as nausea, vomiting, diarrhoea and anorexia; and
- Mania (in patients with manic-depressive illness)

2.9.1.3 Over-the-counter sleep aids

Over-the-counter (OTC) sleep aids are probably used in greater proportions than prescribed hypnotics. Antihistamines (diphenhydramine or doxylamine) form the active ingredients in most of them, and, due to drowsiness being a common side effect people use them to promote sleep. Diphenhydramine or doxylamine cause a paradoxical reaction in some, making people feel nervous, restless and agitated. Taking an OTC sleep aid for more than 7-10 days is not recommended because excessive intake of antihistamines cause constipation, urinary retention, dry mouth, blurred vision, decreased alertness and confusion (especially in the elderly) (Beers, Fletcher, Jones, Porter, Berkwits and Kaplan, 2003: 100).

2.9.1.4 Melatonin

Melatonin is a brain hormone that regulates the body's sleep/wake cycles, (circadian rhythm). It is available over-the-counter, and has become popular in recent years as a dietary supplement for promoting sleep. It has been suggested that changes in melatonin secretion may cause sleep disorders in people with certain nervous conditions. The disadvantage though, is that available preparations of melatonin are unregulated, therefore there is no assurance of its purity and content. The effects of long-term exposure to exogenous melatonin is unknown (Beers and Berkow, 1999: 1413).

2.9.1.5 5-hydroxytryptophan (5-HTP)

5-HTP is related to the amino acid tryptophan. The body uses 5-HTP to manufacture serotonin, which in turn is converted into melatonin in the brain. Thus, 5-HTP is a product that can be used to improve sleep patterns. (Bruni, Ferri, Miano and Verrillo, 2004).

2.9.1.6 Passionflower

Passionflower (*Passiflora incarnata*) has been reported to have sleep-promoting, muscle-relaxing, and pain-relieving properties. Active components of Passionflower may be harmala-type indole alkaloids, maltol and ethyl-maltol, and flavonoids (Miller and Murrey, 1998: 211-212).

Herbalists recommend Passionflower for neuralgia (nerve pain), seizures, hysteria, and rapid heartbeat due to nervousness, asthma, and insomnia. Passionflower extracts have been reported to reduce locomotor activity, prolong sleeping time, raise the pain threshold, and produce an anti-anxiety effect in laboratory animals (Soulimani, Younos, Jarmouni, Boust, Misslin and Mortier, 1997).

In general, Passionflower is considered to be safe and non-toxic. However, there are isolated reports of adverse reactions associated with this herb e.g. nausea, vomiting, drowsiness and a rapid heartbeat. Passionflower is contraindicated during pregnancy and lactation. Due to their active ingredients, interactions with other herbs, supplements, or medication can be triggered (Brinker, 1998).

2.9.1.7 Valerian

Valerian (*Valeriana officinalis*) is used as a calming, relaxing herb that soothes the nervous system under stress. Lindahl and Lindwall (1989) reported that Valerian helps improve sleep quality. Several active ingredients in the herb are believed to account for Valerian's influence, including valepotriates, valeric acid, and pungent oils. These components have a sedative effect on the central nervous system, as well as a relaxing effect on the smooth muscles of the gastro-intestinal tract (Sakamoto, 1992).

Valerian could be taken into consideration as an alternative to drugs in treating insomnia (Gutierrez, Ang-Lee, Walker and Zacny, 2004). Side effects may result which include mild headaches, nausea, nervousness, palpitations and morning drowsiness (Brinker, 1998).

According to Klepser and Klepser (1999), several cases of hepatotoxicity involving long-term use of single-ingredient Valerian preparations have been reported. There is insufficient data to determine the efficacy and safety of Valerian in children younger than 18 years of age and in pregnant women.

2.9.1.8 Hops

Hops (*Humulus lupulus*) is a popular sleep aid. Active ingredients in Hops include valerianic acid, oestrogenic substances, tannins, and flavonoids (Miller and Murrey, 1998: 211-212).

Hops is classified as a herb with hypnotic, antispasmodic, and topical antibiotic properties (Newall, Anderson and Phillipson, 1996: 162). Traditional uses of Hops include neuralgia, insomnia, excitability, topically for skin ulcerations, and primarily for restlessness associated with nervous tension. One study showed improvement of sleep disturbances with combinations of hops and other sedative herbs such as Valerian root and Passionflower (Bradley, 1992: 128 - 129).

Human studies of the sedative action have generally combined Hops with one or more additional herbs. In laboratory studies, Hops have been reported to increase the sleeping time induced by pentobarbital (Lee, Jung, Song, Krauter and Kim, 1993).

2.9.2 NON-PHARMACOLOGICAL INTERVENTIONS

2.9.2.1 Acupuncture

In traditional Chinese medicine, acupuncture is commonly employed for the treatment of insomnia. Montakab (1999), diagnosed 40 patients using Chinese traditional diagnosis. He then performed polysomnographic analyses of true acupuncture versus control needled patients. Objective as well as subjective significant differences in sleep quality were noted in the Treatment Group.

Positive effects using scalp, body, and ear acupuncture points appeared almost immediately after treatment. Several auricular points were used in this study namely, Heart, Kidney, Adrenal, Sub-Cortex, Endocrine, San Chiao, and Shen Men. In addition to these standard 7 auricular points, Sympathetic, Occiput, and Gallbladder auricular points were added if reactive or tender (Montakab, 1999).

The mechanisms by which acupuncture treatment modulates insomnia may be understood in terms of the general mechanism by which it produces analgesia. Sites in the central nervous system where acupuncture signals are integrated also participate in the regulation of sleep-wake cycles (Lin, 1995).

2.9.2.2 Behavioural Therapies

Behavioural therapies seek to change maladaptive sleep habits, reduce autonomic arousal, and alter dysfunctional beliefs and attitudes that are presumed to maintain insomnia (Grunstein, 2002).

Behavioural therapy aims at strengthening the association between sleep behaviours and such stimuli as the bed, bedtime and the bedroom surroundings. The rationale underlying its use is that sleep is a behaviour that is susceptible to conditioning processes. Environmental and temporal stimuli govern the occurrence of sleep at fairly regular intervals. When the stimuli normally conducive to sleep, lose their discriminative properties to do so, treatment must focus on altering these conditions. This is done so that the stimuli can regain their associative control with sleep (Soldatos, 2002 and Morin, 1993: 110).

Behavioural treatment, either utilized in conjunction with pharmacological treatment or alone, is the recommended treatment of choice for patients with chronic primary insomnia (Langer, Mendelson and Richardson, 1999). According to Vincent and Lionberg (2001) patients prefer psychological treatment over pharmacological treatment for chronic insomnia.

Table 2.1 describes various behavioural therapies available for treating insomnia.

Table 2.1 Behavioural therapies for the treatment of insomnia

Name	Description	Reference
Stimulus Control	<p>Reverses conditioned behaviours that are incompatible with sleep. Accomplished by minimizing the amount of time awake in bed, eliminating sleep-interfering activities and regulating the sleep-wake schedule.</p> <p>Considered the standard treatment for primary chronic insomnia. The primary goal of stimulus control is to regain the idea that the bed is for sleeping.</p>	<p>Morin, 1993: 115</p> <p>Sharp, 2001: 121 - 128</p>
<p>Relaxation techniques:</p> <p>Progressive muscle relaxation</p> <p>EMG and EEG biofeedback</p>	<p>Reverses physiological arousal.</p> <p>Aims at reducing somatic arousal.</p> <p>Biofeedback is also effective, but requires being monitored with an electroencephalogram (EEG). Patients are given feedback to recognize certain states of tension or sleep stages so that they can either avoid or repeat them voluntarily.</p>	<p>Langer, Mendelson and Richardson, 1999</p> <p>Grunstein, 2002</p> <p>Lehrer, Sargunarag and Woolfolk, 1994</p>
Sleep restriction therapy	Improved sleep efficiency through partial sleep deprivation.	Langer, Mendelson and Richardson, 1999

2.9.2.3 Cognitive Behavioural Therapy

Cognitive behavioural therapy (CBT) is a form of therapy that emphasizes observing and changing negative thoughts about sleep. It employs actions intended to change behaviour.

A double-blind clinical trial done by Edinger, Wohlgemuth, Radtke, Marsh and Quillian (2001) tested the efficacy of cognitive behavioural therapy (CBT) compared with both muscle relaxation training and a placebo therapy for treating primary sleep-maintenance insomnia. Patients receiving CBT (a combination of sleep education, night time stimulus control, and time-in-bed restrictions) had a significant reduction (54%) in the amount of time spent awake after initially going to sleep and an overall improvement in the quality of sleep. CBT produced larger improvements across the majority of outcome measures than did muscle relaxation training or placebo treatment. This suggests that CBT represents a viable intervention for primary sleep-maintenance insomnia.

2.9.2.4 Sleep Hygiene Tips (Smith, Perlis, Park, Smith, Pennington, Giles and Buysse, 2002) (*Appendix M*)

- Avoid excess caffeine, nicotine and alcohol
- Set aside 'worry time' in the evening (away from the bedroom) where you can go through current problems and the next days' commitments
- Limit bed to sleep and sex – avoid reading, listening to the radio and watching television.
- Exercise in the early morning sunlight to strengthen normal sleep circadian rhythms
- Avoid strenuous exercise after 6pm
- Avoid napping during the day
- Plan for bedtime – eat a small snack or have a warm bath before bed
- Be sure that the mattress is not too soft or too firm, and that the pillow is at the right height and firmness
- Keep the clock face turned away, and do not find out what time it is when you wake up at night

2.10 HOMOEOPATHY AND THE SIMILLIMUM

2.10.1 DEFINITION

'Homoeopathy' is derived from the Greek words '*Homoeo*', meaning 'like' and '*Pathos*', meaning 'suffering'. Homoeopathy is a system of medicine that uses preparations of substances whose effects, when given to healthy individuals corresponds to the manifestations of the disease (symptoms, clinical signs and pathological states) in the individual (Swayne, 2000: 105).

A German physician, Dr. Samuel Hahnemann (1755-1843), founded this system of medicine. The foundation of Homoeopathy is "Like Cures Like". This principle states that a substance which produces certain symptoms in healthy people can cure the same symptoms in the sick. The substance must be administered in minute doses (de Schepper, 2001: 26).

2.10.2 LAWS AND PRINCIPLES OF HOMOEOPATHY

Homoeopathy as a system of medicine follows certain laws and principles. These include:

- Law of similars
- The minimum dose
- Single remedy prescription

In the *Organon of the Art of Healing*, Hahnemann laid out the laws and principles of homoeopathy, gathered over a period of 20 years. Briefly, he claimed and showed that:

1. A medical cure is brought about in accordance with certain laws of healing that are in nature.
2. Nobody can cure outside these laws.
3. There are no diseases as such, but only diseased individuals.
4. An illness is always dynamic by nature, so the remedy must also be in a dynamic state if it is to cure.
5. The patient needs only one particular remedy and no other at any given stage of the illness. Unless that certain remedy is found, he or she is not cured but at best the condition is only temporarily relieved (Vithoulkas, 2000: 6).

The statement “*Similia similibus curentur*” (“like cures like”) was first pronounced by Paracelsus and was later re-discovered by Hahnemann. This statement has been formalised in the law of similars. Hahnemann proceeded to build upon this fact his superstructure of scientific treatment by medicinal substances. Any substance, it may be of animal, vegetable or mineral origin, will produce certain reactions or symptoms, if given to the healthy individual for a long enough period (Shepherd, 1995: 6).

These reactions were collected by Hahnemann and his pupils with great diligence. It followed that these self-same symptoms, if found in a sick person, would be cured by the medicinal substance which produced them in the healthy individual. This was tested and proved by Hahnemann and his followers more than 150 years ago. Provings, as he called these experimental tests, were carried out on healthy human beings. A number of people were chosen and their peculiarities were noted. They received blank pills or powders for several days, then a medicinal substance was added without their knowledge, and any reactions or symptoms that were produced were noted, and a record was drawn up for each remedy proved. In that way nearly 106 medicinal substances were proved. Now homoeopaths possess a *Materia Medica* of approximately 2000 remedies from which to choose according to the law of similars the correct remedy for each case (Shepherd, 1995: 8 and Kayne, 1997: 25 - 28).

The similarity between pathogenesis and treatment is therefore vital in understanding the law of similars. Figure 2.4 illustrates this similarity.

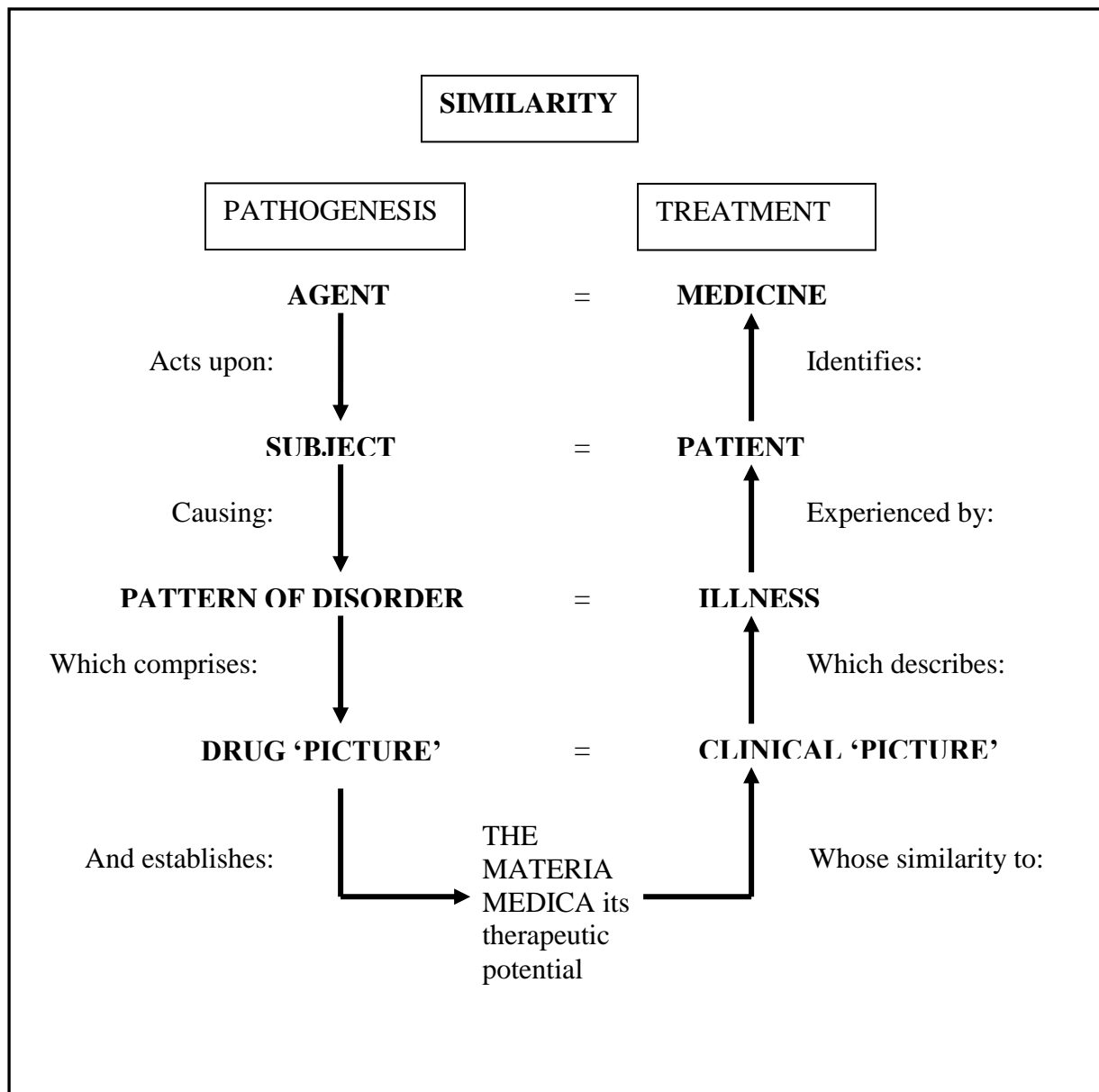


Figure 2.4 Similarity between pathogenesis and treatment (Swayne, 1998: 19)

2.10.2.1 Law of Similars

The fundamental principle underlying homoeopathy is the law of similars. This law refers to a similarity existing between the toxicological action of a substance and its therapeutic action (Jouanny, 1993: 11).

According to Jouanny (1993: 11-13), there are three components to this law:

1. All pharmacologically active substances cause a set of symptoms characteristic of the substance used when administered to healthy people.
2. All sick individuals display a set of symptoms characteristic of their disease (broader than the 'diagnostic criteria').
3. The cure may be achieved by prescribing the substance whose experimental symptoms in healthy people are most similar to the symptoms displayed by the ill patient. The substance must be administered in infinitesimal doses.

2.10.2.2 The Minimum Dose

Amedeo Avogadro (1776 – 1856) demonstrated that the number of molecules in one mole of any substance is 6.0255×10^{23} . Avogadro's number is of interest to homoeopathy because it specifies the potency at which a remedy does not contain any of the original material substance. (Swayne, 2000: 22).

Avogadro's number is exceeded at a potency of 12CH in concentrated pure chemical substances, including metals and between 7CH to 11CH in botanical or zoological materials (Kayne, 1997: 27).

According to Shepherd (1995: 5), the Arndt's Law helps to explain the phenomenon of potentization (as discussed in 2.10.8 later). The law was based on the following observations:

- Small stimuli encourage living systems
- Medium stimuli impede living systems
- Strong stimuli destroy living systems

Thus, as solutions of homoeopathic remedies become weaker, they should be expected to encourage the healing process. According to Osawa (2001), the smallest dose will evoke the most gentle, rapid and permanent cure. There is a homoeopathic Law of Cure associated with minute dose levels. It states;

“The quantity of action necessary to effect a change in nature is the least possible, and the decisive amount is always the minimum.”

The minute dose was an empirical discovery, and it is taken to mean that not only should a minute dose be administered, but that the dose should not be repeated at frequent intervals (Kayne, 1997: 27).

2.10.2.3 Single Remedy Prescription

This principle refers to the administering of only one dose of a single homoeopathic medicine, which is derived from one source material at any one time. This is the basis of unicist homoeopathy, often termed classical homoeopathy (Swayne, 2000: 195).

According to Eizayaga (1991), there is usually only one remedy that covers the actual state of the patient and therefore only the most similar should be administered. When the symptoms change, it becomes, necessary to prescribe a new remedy according to the patient's new state.

If a combination of remedies is administered, the potential interactions that may occur between the components cannot be predicted. In addition any beneficial or adverse effects cannot be evaluated correctly, as there is no way to decide which one of the remedies of a combination has acted (Vithoulkas, 1998: 217).

2.10.3 VITAL FORCE

An important concept of homoeopathy is that, in all conditions of ill health, the human body is fully capable of healing itself by means of the vital force. Ancient physicians were familiar with the natural power of an organism to control disease and they expressed it as “*Vis Medicatrix Naturae*” (*healing power of nature*).

Hahnemann called this healing power the vital force. Disease is seen as a manifestation or reflection of the disturbed vital force (Sankaran, 1991: 2).

2.10.4 SIMILLIMUM

The aim of the homeopathic consultation and analysis is to arrive at the simillimum. Simillimum treatment is based on a full evaluation of the patient's physical, emotional and mental characteristics (Lockie and Geddes, 1995: 14).

To do this, the homoeopath takes into consideration all symptoms that distinguish a person as an individual. There is an enquiry into the patient's past and family history, his appetite, thirst, bowel habits, sleep and his temperament, amongst others (Sankaran, 1991: 2).

Homoeopathic remedies are tailored not only to the patients' symptoms but also to their personality types and the reason for their illness. With the vast number of remedies to choose from, homoeopaths reason that the simillimum will fit the

patient on a dynamic plane, acting as a template by means of which the disordered vital force can readjust itself (de Schepper, 2001: 3 - 11 and Weiner and Gross, 1989: 53).

The selected remedy, in order to be the true simillimum, must match not only the patient's symptoms but also the dynamic plane of the disease at the time the patient presents himself for treatment (Weiner and Gross, 1989: 58).

According to Gaier (1991: 509), the simillimum remedy refers to that single, unique remedy, the drug picture of which most nearly approaches the total symptom complex of the patient.

After the simillimum remedy has been given, not only are the symptoms alleviated but the patient should also have a sense of well-being (Eizayaga, 1991: 11, 37). This is because the vital force is strengthened and balanced resulting in restoration of the entire spiritual-mental-emotional-physical being (de Schepper, 2001: 3 - 11).

2.10.5 HOLISM AND HOMOEOPATHY

Vital to developing the homoeopathic vision is to understand that disease is not merely something local, but it is a disturbance of the whole being. The mental state of the diseased individual often chiefly determines the prescription of the homoeopathic remedy (Sankaran, 1994: 11, 15).

By 1813, Hahnemann concluded that the curative action of a drug lies in its dynamic effect, and not in its local organ effect. With present medical knowledge, we understand that the mind acts on the body through three systems, thus forming the Psyche-Neuro-Endocrine-Immunology (P-N-E-I) axis. These systems are intricately connected, such that changes in Psyche have an association with certain symptoms in the NEI-systems. This axis controls and regulates other systems. Homeopathic drugs cause a dynamic disturbance that must act through this axis (Sankaran, 1991: 36-37).

2.10.6 POTENCY

Homoeopathic potency consists of medicinal matter raised to high rates of vibration, stimulating the vibratory rate of the vital force of the patient (Bernard, 1999). Dynamization (potentization) arouses the latent medicinal properties in natural substances during the processes of dilution and succussion.

Succussion is the addition of kinetic energy to the remedy by virtue of vigorous shaking (Boericke, 1997: 19). The more a substance is succussed and diluted the greater the therapeutic effect while any toxic effect is simultaneously abolished (Vithoulkas, 1980).

Homoeopathic dilutions are rendered by either the centesimal scale (1:100), denoted by "C", or the decimal scale (1:10) to which resulting potencies are designated "X". Thus in practice the first 1:100 dilution is termed a 1C and the thirtieth dilution 30C. The first 1:10 dilution is called a 1X and the thirtieth a 30X (Vithoulkas, 1980).

Hahnemann spent the last decade of his life developing the fifty millesimal (LM) potencies. LM potencies are made by diluting the remedy in a ratio of 1: 50 000 (de Schepper, 2001).

2.10.7 POTENTISED MEDICINE

Towsey and Hasan (1995) view the action of potentized homoeopathic medicines, as being biophysical and not biochemical. They suggest that such medicines probably consist of water crystals imprinted with specific distribution of isotopes. This distribution affects the frequencies at which water components within the medicine absorb and emit coherent radiation. These coherent emissions either enhance or inhibit enzyme action.

They explain that modulated magnetic or electric fields are able to give water crystals a stable conformation. Subtle energies, they concluded, not only imprint molecular and crystalline structures but are able to have an effect on the supramolecular dynamic order of living things.

2.11 HOMOEOPATHIC TREATMENT OF INSOMNIA

There is much literature about homoeopathic remedies used to treat insomnia. Unfortunately, there is paucity in controlled clinical trials based on the efficacy of homoeopathic treatment for chronic primary insomnia.

2.11.1 HOMOEOPATHIC SIMILLIMUM TREATMENT OF SECONDARY

INSOMNIA IN PERI- AND POSTMENOPAUSAL WOMEN (Pellow, 2002)

Pellow (2002) conducted a qualitative study which examined the efficacy of the homoeopathic simillimum approach in the treatment of secondary insomnia in peri- and postmenopausal women. Homoeopathic remedies were prescribed in LM potency, taken once daily, and the patient's progress was noted over the 3 month duration of the trial. This consisted of an initial consultation and 6 Follow-Up consultations at 2 week intervals. According to the study, homoeopathic simillimum treatment helped decrease fatigue and sleepiness in varying degrees in each subject and improved the subjects' perception of the quality of their sleep.

This study produced positive results although there were potential methodological flaws present. It was not a double-blind-placebo-controlled study and the sample size of the study was small ($n = 10$).

LM potencies were used which may have been restrictive. Each participant was asked to success the bottle each day before taking a dose, giving the bottle eight hard blows against the palm of the hand. One teaspoon of the remedy was then stirred into 100ml of water and taken once a day. The use of this method of administration of the remedy may have led to difficulties with compliance.

Unrestricted simillimum studies, however, would allow for the use of remedies in any potency, including LM potencies.

In cases where the remedy's action appeared to aggravate the insomnia, participants were advised, by Pellow, to stop taking the remedy until the aggravation had passed. In cases where the participants were not responding adequately to the remedy, as reported by the participant and perceived by the researcher, they were advised to increase the frequency of the dose. This results in significant inconsistencies in treatment administration in the study.

Participants using hormone replacement therapy (HRT) were not excluded, as subjects with insomnia despite HRT were considered suitable, by the researcher, for the study. Oestrogen has powerful effects on several biological factors that directly influence sleep, including body temperature regulation and circadian rhythms. Oestrogen therapy most likely improves sleep as it alleviates vasomotor symptoms (Moe, 1999). Boyle and Murrihy (2001), reported that women who use HRT have decreased anxiety, less insomnia and fewer somatic symptoms.

Therefore, it is difficult to assess whether the homoeopathic treatment or a combination of the homoeopathic treatment and HRT was effective in alleviating secondary insomnia in the study.

The study made use of the Stanford Sleepiness Scale (SSS) (Hoddes, Zarcone, Smythe, Phillips and Dement, 1973) and a Sleep Diary. The SSS was used to determine each participant's subjective assessment of sleepiness in the morning, at lunch-time and in the evening every day for the duration of the study. The scale consists of seven statements that range from being wide awake and alert to being almost in a state of sleep (Hoddes, et al. 1973). Participants were asked to record the number between one and seven that best described their level of sleepiness. A Sleep Diary provided an indication of perceived total sleep time per night and number of nightly awakenings. The information given in each questionnaire was evaluated and was used together with information obtained at each consultation to compile a descriptive study of individual cases. There was no use of statistical analysis of the SSS and Sleep Diary readings, which would have expanded the subjective perceptions of the improved quality of sleep following homoeopathic intervention.

According to Neuman (2000: 418), qualitative data analysis is less standardized. The wide variety in possible approaches to qualitative research is matched by the many approaches to data analysis. Quantitative researchers, on the other hand, choose from a standardized set of data analysis techniques. Quantitative analysis is highly developed and builds on applied mathematics (Neuman, 2000: 418). Due to the paucity of quantitative, double-blind-placebo-controlled clinical studies evaluating the efficacy of homoeopathic simillimum in the treatment of chronic primary insomnia; there is a need for further studies.

2.11.2 THE EFFECT OF AVENA SATIVA COMP[®], A HOMOEOPATHIC COMPLEX REMEDY, ON SUBJECTIVE SLEEP MEASURES IN SUFFERERS OF SECONDARY INSOMNIA (Roohani, 1997)

Roohani (1997) showed that *Avena Sativa Comp[®]* decreased fatigue and evening sleepiness and improved subjective perception of sleep quality in self-diagnosed secondary insomniacs. *Avena Sativa Comp[®]* is manufactured by the pharmaceutical company, *PharmaNatura* (Pty) Ltd and contains the following in its 100ml dropper bottles:

- | | |
|---|---------|
| • Avena sativa (herbal tincture) | 25ml |
| • Humulus lupulus 1X | 4ml |
| • Passiflora incarnate (herbal tincture) | 7.5ml |
| • Valeriana officinalis (herbal tincture) | 30ml |
| • Coffea tosta D60 | 15ml |
| • Nominal Ethanol content | 45% v/v |

Ten male subjects complaining of secondary insomnia formed the sample group. They underwent a 14 day screening period, during which time they completed questionnaires relating to sleep.

The measurement tools used included a Sleep Diary, a Profile of Mood States (POMS) (McNair, Lorr and Droppelman, 1971: 27) form to assess psychological status, and an assessment of day-time sleepiness using the Stanford Sleepiness Scale (SSS) (Hoddes, et al. 1973). Analogue scales were used to indicate the subjective assessments of quality of the previous nights sleep (morning form) and to give an indication of the subject's anxiety levels during the day (evening form).

Each participant was required to complete a Sleep Diary for the duration of the study, to provide an indication of total sleep time per night and the number of nightly awakenings.

The POMS (McNair, Lorr and Droppelman, 1971: 27) was used to determine the mood states of the subjects, including tension-anxiety, depression-dejection, anger-hostility, vigour, fatigue and confusion-bewilderment. Scores were determined for each scale of the POMS questionnaire using the POMS scoring system.

The SSS (Hoddes, et al. 1973) was used to determine daily subjective assessments of sleepiness in the morning, at lunchtime and in the evening for the 42 days of the study.

Participants were admitted to the study provided they had a minimum of four sleep deprived nights in the 14 day screening period. Thereafter the participants entered a double-blind crossover trial when the homoeopathic complex or placebo was administered nightly, for 14 days.

Statistical analysis using Instat, Instant Statistics, San Diego, California, Version 2.0. was conducted using all measurement tools. The Friedman test, combined with the Dunn's statistical test to identify the origin of significance were used. Significance was set at $p \leq 0.05$.

The study concluded that *Avena Sativa Comp*[®] helped decrease fatigue ($p < 0.0001$) and evening sleepiness, and improved the subject's perception of the quality of their sleep.

This study produced positive results although there were potential methodological flaws present. Expansion of the sample size, as well as the inclusion of females into the study may have further validated the results. The placebo and treatment was administered by placing ten drops in half a glass of water after supper in the evening and just before going to bed. Participants could also take the medication if they awoke during the night. They were requested to record this information in their Sleep Diary. This results in significant inconsistencies in treatment administration in the study.

According to Lavery (1997: 28 – 36), there are many causes of secondary insomnia. These include:

- MEDICAL CAUSES such as:

Non-prescription drugs e.g. caffeine, nicotine and 'diet pills'

Prescription drugs e.g. Ritalin[®], Ventolin[®], Cardioquin[®] and Cylert.[®]

- MEDICAL CONDITIONS such as:

Pain from any source or cause

Thyrotoxicosis

Dyspnoea from any cause

Drug or alcohol intoxication or withdrawal

Depression

Post-traumatic stress disorder

Mania or hypomania

The sample group in Roohani's study may not have been a homogenous group due to the various causes of secondary insomnia. Although the findings of the study were positive, the administration of complex homoeopathic remedies is in conflict with the principle of single remedy prescription (Kayne, 1997: 27). It is not necessary, and therefore not permissible to administer more than one, single homoeopathic medicinal substance to a patient (Vithoulkas, 1998: 217). All drug pictures in the materia medica have

been determined on this basis. Provings have not been carried out on complexes of remedies and it is not known how and if remedies interact (Kayne, 1997: 28).

2.11.3 THE EFFECT OF HOMOEOPATHIC SIMILLIMUM IN POST TRAUMATIC STRESS DISORDER (Lankesar, 2004)

Lankesar (2004) researched the efficacy of simillimum treatment for post-traumatic stress disorder. Each participant completed the researcher's questionnaire at each consultation and recorded their stress episodes on a calendar. The information from the stress episodes calendar was evaluated and was used together with information obtained at each consultation to compile a descriptive study of individual cases. Statistical analyses, of the findings from the measurement tools, were not conducted.

This qualitative study indicated that the simillimum treatment was effective in reducing post traumatic stress frequency, severity and intensity. According to case histories, improvement in mental and emotional well-being, sleep patterns and energy levels were noted in all patients. The insomnia experienced by the participants can be classified as secondary insomnia.

This study produced positive results although there were potential methodological flaws present. It was not a double-blind-placebo-controlled study and the sample size of the study was small (n = 10).

2.12 MEASUREMENT TOOLS

Insomnia is a subjective complaint of insufficient or inadequate sleep. It occurs with few physical signs, and is defined largely on the basis of the patient's self report (Aldrich, 1993).

In this study, subjective questionnaires were used namely, a Sleep Diary (*Appendix A*), the Sleep Impairment Index (SII) (Morin, 1993: 199) (*Appendix B*) and the Dysfunctional Beliefs and Attitudes about Sleep Scale (DBAS) (Morin, 1993: 201-204) (*Appendix C*).

2.12.1 SLEEP DIARY (*Appendix A*)

A Sleep Diary is a daily, written record of an individual's sleep-wake pattern containing such information as time of retiring and arising, time in bed, estimated total sleep period, number and duration of sleep interruptions, quality of sleep, daytime naps, use of medications or caffeine beverages, nature of waking activities and other data (Kryger, Roth and Dement, 1998).

Sleep diaries can provide clinically useful information in the initial assessment of the complaint, particularly as it relates to the patient's perception of the problem. But it has not been shown to differentiate subtypes of insomnia complaints (Chesson, Hartse, Anderson, Davila, Johnson, Littner, Wise and Rafecas, 2000).

Bakea (2003) suggested the inclusion of a subjective Sleep Diary. It had been designed by a patient of the sleep lab and was used by Bakea as a subjective measurement against polysomnograph readings. The Sleep Diary was suggested for use as a simple means for recording times asleep and awake.

The SII (*Appendix B*) and DBAS (*Appendix C*) are subjective and retrospective. They provide important information regarding psychological and behavioural aspects of the sleep complaint (Morin, Stone, McDonald and Jones, 1994).

According to Smith and Trinder (2001), the SII and DBAS distinguished effectively between the insomnia and control groups suggesting good specificity. They were found to be highly accurate discriminators and offer similar sensitivity in detecting insomnia. Self-report remains the easiest, cheapest and most widely used method of collecting data about an individuals' health and risk factor status.

A number of relatively brief self-report measures have been developed to detect and quantify sleep impairment and insomnia. These include the Sleep Impairment Index (SII) (Morin, 1993) (*Appendix B*) (Smith and Trinder, 2001) and the Dysfunctional Beliefs and Attitudes About Sleep Scale (DBAS) (Morin, 1993) (*Appendix C*).

2.12.2 SLEEP IMPAIRMENT INDEX (SII) (*Appendix B*)

The SII is a 7-item measurement tool that yields a quantitative index of sleep impairment. It is a brief and global self-report instrument which provides valuable information on the patient's perception of his or her insomnia, its severity, level of distress and impairment with daytime functioning (Morin, 1993: 73).

The SII has been found to be sensitive to changes in insomnia outcome research. It is a reliable and valid measure for the assessment of insomnia severity in a clinical population. The instrument is a cost-efficient method to quantify perceived insomnia severity and may be used either as a screening device or as a measure of treatment outcome (Bastien, Lamoureux, Gagne and Morin, 2004).

Although very brief, the sensitivity and specificity of the SII is sufficient for identification of insomnia in primary care settings (Smith and Trinder, 2001).

2.12.3 DYSFUNCTIONAL BELIEFS AND ATTITUDES ABOUT SLEEP SCALE

(DBAS) (*Appendix C*)

Dysfunctional beliefs and attitudes about sleep are presumed to play an important role in perpetuating insomnia. The DBAS is a 30-item questionnaire designed to tap sleep-related cognitions. This instrument has proved extremely useful as a therapeutic tool for conducting cognitive therapy sessions. It helps to identify dysfunctional sleep-related cognitions and provides data on both treatment process and outcome (Morin, 1993: 73).

Belleville, Belanger and Morin (2003) utilized the DBAS when assessing the usefulness of cognitive-behavioural therapy in changing sleep-related beliefs and attitudes in older insomniacs discontinuing their benzodiazepine hypnotic treatment. The DBAS proved extremely useful as it was used to evaluate the erroneous sleep-related cognitions in 76 older adults.

The DBAS provides useful information relevant to intervention into insomnia. It contains sufficient items to increase the probability of test reliability and is recommended for use in a sleep clinic environment (Smith and Trinder, 2001).

2.13 PLACEBO

2.13.1 DEFINITION

A placebo is an inactive substance or preparation formerly given to please or gratify a patient, now also used in controlled studies to determine the efficacy of medicinal substances (Dorland's Illustrated Medical Dictionary, 1994: 1298).

2.13.2 PLACEBO EFFECT

The use of placebos may result in or be coincidentally associated with desirable or undesirable changes. This phenomenon is known as the placebo effect. It has two components:

- Anticipation of results due to an optimistic outlook. It is sometimes referred to as suggestibility and
- Spontaneous change. Some people improve spontaneously, without treatment. If this occurs, the placebo may incorrectly be “credited with or blamed for the result” (Beers, et al. 2003: 61).

The placebo effect is considered as an example of mind-body relation that depends on subconscious interactions between the doctor, the treatment process, and the patient. A physician's attributes, dress, demeanor, voice and body language each contribute to a marked placebo effect. The benefit of

placebo is considered transient, although its effects are not always short-lived (Pearce, 1995).

Some scientists believe that homoeopathy goes against natural laws, and any effect produced by homoeopathic treatment, is due to the placebo effect. But the use of and growing belief in the effectiveness of homoeopathy, is widespread, and a scientific meta-analysis of published studies has concluded that there are measurable and reproducible effects compared to placebo (Linde, Clausius, Ramirez, Melchart, Eitel, Hedges and Jonas, 1997).

2.14 CONCLUSION

Chronic insomnia, if untreated, can have social, economic and occupational impacts on the individual, as they are not functioning at their optimum (Morin, 1993: 9). There is a paucity of double-blind-placebo-controlled studies based on the efficacy of homoeopathic simillimum in the treatment of chronic primary insomnia.

There are many side effects of allopathic drugs used to treat insomnia, therefore clinical studies should be conducted to question other treatment modalities (Roth, Roehrs, Costa e Silva and Chase, 1999: S419).

CHAPTER 3

METHODS AND MATERIALS

3.1 PROBLEM STATEMENT

The purpose of this double-blind placebo-controlled study was to evaluate the efficacy of homoeopathic simillimum in the treatment of chronic primary insomnia in terms of the patient's perception of the treatment using a Sleep Diary (*Appendix A*), the Sleep Impairment Index (SII) (Morin, 1993: 199) (*Appendix B*) and the Dysfunctional Beliefs and Attitudes about Sleep Scale (DBAS) (Morin, 1993: 201-204) (*Appendix C*).

3.2 SAMPLE GROUP

All the measures and procedures that were used in the study were approved by the Faculty of Health Sciences Ethics Committee at the Durban Institute of Technology. 30 participants were selected via convenience sampling and were recruited on the basis of inclusion and exclusion criteria.

3.2.1 INCLUSION CRITERIA

Participants were selected for the study according to the following criteria:

1. Participants had to be between the ages of 18 years to 70 years.
2. Participants had to be fluent in English.
3. Participants had to be literate in English.
4. Participants had to have taken no other prescribed insomnia medication for at least one week before the study. Use of over-the-counter sleep aids and prescription insomnia medication were prohibited during the study.
5. Participants had to fulfil the diagnostic criteria for 307.42 Primary Insomnia according to Diagnostic and Statistical Manual of Mental Disorders, 4th edition Text Revision (DSM-IV TR) (2000: 604).
 - A. The predominant complaint is difficulty initiating or maintaining sleep, or
 - B. Nonrestorative sleep, for at least 1 month.
 - C. The sleep disturbance (or associated daytime fatigue) causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.
 - D. The sleep disturbance does not occur exclusively during the course of Narcolepsy, a Breathing-Related Sleep Disorder, Circadian Rhythm Sleep Disorder, or a Parasomnia.
 - E. The disturbance does not occur exclusively during the course of another mental disorder (e.g. Major Depressive Disorder, Generalised Anxiety Disorder, a delirium).

F. The disturbance is not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition.

3.2.2 EXCLUSION CRITERIA

Participants were excluded from the study according to the following criteria:

1. Pregnant women.
2. Participants suffering from Narcolepsy, a Breathing-Related Sleep Disorder, Circadian Rhythm Sleep Disorder, or a Parasomnia. (*Appendix E*).
3. Participants diagnosed with Major Depressive Disorder, Generalised Anxiety Disorder or Schizophrenia (*Appendix F*).
4. Participants diagnosed with hyperthyroidism, hypertension, diabetes and hypercholesterolemia.

3.3 LOCATION OF THE STUDY

Consultations were conducted at the Homoeopathic Day Clinic at the Durban Institute of Technology, Steve Biko Campus, Berea. Consultations were conducted on weekdays between 13h30 and 16h30.

3.4 RECRUITMENT PROCESS

Participants responded to advertisements that were placed on notice boards at the Durban Institute of Technology as well as local newspapers. An article was placed in the “Tribune Herald” on 18 April 2004 (*Appendix G*). The article, entitled “Bye-bye drowsiness – student offers help in beating sleepless night blues,” indicated that the researcher was recruiting individuals with chronic primary insomnia to evaluate homoeopathic treatment for the condition. The article informed potential participants about homoeopathy, the inclusion and exclusion criteria for the clinical trial, the free homoeopathic treatment and that their participation was on a voluntary basis. The researcher’s telephone number was included for further information.

Approximately 109 interested individuals contacted the researcher about the study and participated in a brief telephone screening interview which verified inclusion and exclusion criteria (*Appendix H*). Of these, 21 people did not meet the inclusion criteria for chronic primary insomnia. 88 individuals were asked to contact the Homoeopathic Day Clinic to make appointment bookings. The first 30 callers, who had passed the telephone interview, were given appointments. The remainder of the callers were put on a waiting list.

During the study, there were 3 drop-outs from treatment. Reasons for dropping out included scheduling conflicts, personal issues and non-compliance with regards to taking the homoeopathic medication.

Three people from the waiting list were then invited to participate in the trial to accommodate for the drop-outs.

3.5 ETHICAL ISSUES

In this study, homoeopathic simillimum was compared to placebo in its effectiveness in treating chronic primary insomnia. Apart from participants being divided into Treatment and Placebo Groups, they were treated equally in all spheres.

Before the initial consultation, participants were given a subject information letter (*Appendix I*) to read. This informed participants of consultation times and assured them of the strict confidentiality with which all information was maintained. The researcher explained the need for the use of placebo for comparative purposes and that there was a 50% chance that they may be placed on the Placebo Group. Chronic primary insomnia is not considered a life threatening condition; therefore, participants were not placed in any serious health risk if they were to receive placebo powders. All participants were informed that upon unblinding, if it

were discovered that they received placebo, the relevant homoeopathic remedy would be given to them at the end of the study, free of charge.

If they met the selection criteria and were willing to participate further, they were given an informed consent form (*Appendix J*) to sign. Participants understood that they were free to withdraw from the study at any time, without having to give a reason for withdrawing and without affecting their future health care. All participants agreed to participate voluntarily in the study.

3.6 RANDOMISATION AND BLINDING

This was a double-blind study. Participants were assigned numbers sequentially as they entered the study. The numbers corresponded to 30 numbers randomly allocated into two groups (by means of drawing from a hat) forming a randomisation sheet (*Appendix K*) drawn up by the research supervisor.

Fourteen participants were selected for the Treatment Group and sixteen for the Placebo Group. During the study, neither the participant nor the researcher was aware of which group the participant belonged to. Dispensing of medication was performed by the assigned laboratory technician at the Homoeopathic Day Clinic, according to the randomisation sheet. The randomisation sheet was revealed to the researcher once all 30 participants had completed their three consultations. Participants that received placebo were then called to collect their homoeopathic remedies, free of charge.

3.7 TREATMENT

Treatment consisted of approximately 10 medicated lactose granules which were placed into sachets containing lactose powder. The medicated granules were produced in accordance with method 10 (*Appendix N*) of the German Homoeopathic Pharmacopoeia (British Homoeopathic Association, 1991).

Lactose granules were impregnated with centesimal potencies of the relevant remedy, using 96% alcohol, prepared by Natura laboratories. A triple impregnation of the lactose granules at 1% v/v was conducted. Approximately 10 granules of the relevant remedy was then inserted into paper sachets containing lactose powder, as individual lactose powders act as an ideal means of conveyance for one single dose.

The participants in the Placebo Group received approximately 10 unmedicated granules which were triple impregnated with 96% alcohol only. These granules were then placed into sachets. The placebo powders were thus indistinguishable from the treatment powders.

Each participant was given 6 powders - 3 powders at the first consult and 3 powders at the second consult.

The laboratory technician at the clinic dispensed the relevant medication according to the randomisation list. All participants were also given an instruction sheet for further clarification (*Appendix D*). Each participant was given clear instructions to dissolve a sachet of the remedy under their tongue at bedtime. This had to be adhered to for three consecutive nights. They were also told to abstain from any other insomnia treatment for the duration of the study.

The researcher emphasized the importance of complying with all instructions. All possible measures were taken to ensure that instructions were correctly adhered to. Participants were encouraged to question the researcher or the laboratory technician should any ambiguities or concerns with regards to taking the medication arise. A participant who did not comply with instructions was discontinued from the study. The remaining participants reported that there was no confusion concerning instructions about taking the homoeopathic medication and no irregularities arose. The researcher assumed that all participants were honest in their reporting. An assumption of the study was that the participants took the homoeopathic remedies as prescribed.

3.8 CONSULTATION PROCEDURES

Participants consulted with the researcher 3 times during the study. After the initial consultation, there were 2 Follow-Up consultations at 2 week intervals. Participants' involvement in the study ended after this 4 week period.

3.8.1 FIRST CONSULTATION

1. This began as soon as the subject information letter (*Appendix I*) was read and the informed consent form (*Appendix J*) was signed.
2. A full homoeopathic case history was taken and a physical examination was performed to screen for any associated medical conditions that may have existed (*Appendix L*).
3. Participants were required to complete the DBAS (*Appendix C*) and the SII (*Appendix B*). This was done before they received any treatment so as to provide a baseline measurement for statistical purposes. Each participant was instructed to start a Sleep Diary (*Appendix A*) where they noted the hours slept for 1 week before taking the medication, so as to provide a baseline measurement for statistical purposes. Recordings of the Sleep Diary was continued throughout the trial. Medication was instructed to be taken on the eighth night after the initial consultation (i.e. after 1 week without any medication, during which time participants were to record the hours slept only).
4. Participants were sent to the clinic reception area to collect their prescription.
5. The homeopathic dispenser on duty at the Homoeopathic Day Clinic dispensed the relevant medication to the respective groups according to the randomization sheet drawn up by the supervisor.

6. Treatment consisted of 3 powders containing either the simillimum or placebo.
7. Each participant was required to take one powder daily, at bedtime on the eighth, ninth and tenth day after the initial consultation.
8. Participants were asked to return for the second consultation two weeks later.

3.8.2 FOLLOW-UP ONE

1. This was a Follow-Up consultation which included checking of the vital signs.
2. The Sleep Diary was collected.
3. The patient was re-evaluated. The researcher either:
 - a) repeated the medication
 - b) changed the potency of the initial medication
 - c) changed the remedy or
 - d) left the remedy to act.

The above 4 options are consistent with standard practice in homoeopathic simillimum treatment (Naude, 2005).

4. Participants were asked to complete the DBAS (*Appendix C*) and the SII (*Appendix B*). Participants were asked to complete a Sleep Diary and bring it to the next consult.
5. Each participant was required to take one powder daily, at bedtime for 3 consecutive nights.
6. Participants were asked to return for the third consultation two weeks later.

3.8.3 FOLLOW-UP TWO

1. The Sleep Diary was collected and
2. The vital signs were examined.
3. Participants were asked to complete the DBAS (*Appendix C*) and SII (*Appendix B*).
4. Participants were given sleep hygiene rules developed by the Sleep Society of South Africa (*Appendix M*).

Figure 3.1 contains a summary of the consultation time-line.

On completion of the study, participants from the Placebo Group were telephonically contacted, and invited to collect their medication (i.e simillimum) which they received free of charge. Various remedies were prescribed during the study.

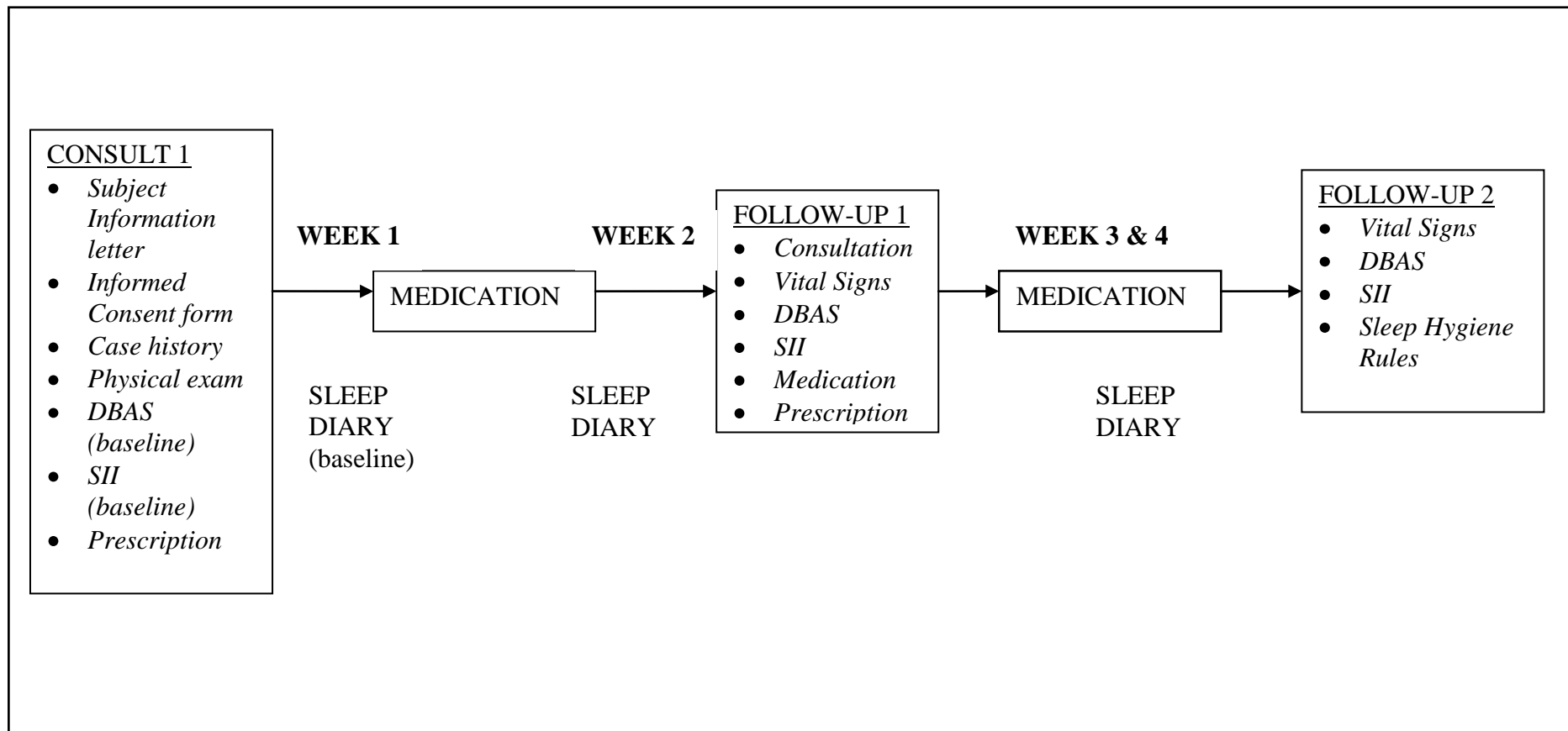


Figure 3.1 Summary of consultation time-line

3.9 DATA COLLECTION

Patients were assessed using the Sleep Diary (*Appendix A*), the SII (*Appendix B*) and DBAS (*Appendix C*).

3.9.1 MEASUREMENT TOOLS

3.9.1.1 Sleep Diary

Participants marked the times that they were awake and asleep every 24 hours. They were also required to write the total hours of sleep that they attained every 24 hours. This was recorded for one week before commencement of homoeopathic treatment so as to serve as a baseline measure. On the eighth night following the initial consultation, participants were required to take the medication at bedtime. This had to be repeated for 3 consecutive nights. The Sleep Diary was maintained throughout the study. Data was analysed at the end of the study in terms of total hours slept per week, as well as net gains/loss in hours slept per week in comparison to the baseline week.

3.9.1.2 Sleep Impairment Index

Participants were instructed to answer all questions as objectively and as accurately as possible. Participants graded each question according to the severity of their symptoms. This included difficulty falling asleep, difficulty staying asleep and problems waking up too early. They graded their dissatisfaction about their sleep problem and problems with cognitive disturbances (racing thoughts at night) as well. Each question received a score according to whether the participant graded it as 'none', 'mild', 'moderate', 'severe' or 'very much'. The questionnaire was completed and scores were given at the first consultation (baseline measurement), after the second consultation (Follow-Up 1) and after the third consultation (Follow-Up 2).

3.9.1.3 Dysfunctional Beliefs and Attitudes about Sleep Scale

Participants were instructed to answer all questions as objectively and as accurately as possible. They were instructed to indicate to what extent they personally agree or disagree with each statement. Participants graded each statement according to the severity of their symptoms. The questionnaire was completed and scores were given at the first consultation (baseline measurement), after the second consultation (Follow-Up 1) and after the third consultation (Follow-Up 2).

3.9.2 STATISTICAL ANALYSIS

Statistical analysis was conducted using the SPSS (version 12.1) software suite. This statistical software program is manufactured by SPSS Inc, 444N. Michigan Avenue, Chicago, Illinois, USA. Various descriptive and inferential statistical techniques were used. The descriptive procedures used were various tables and graphs and a few summary statistics including but not limited to means, proportions and percentages. Inferential statistics included various hypothesis testing techniques. Due to the size of the sample, non-parametric statistical tests were used. All tests set the type 1 error at 5%, or mentioned differently $\alpha = 0.05$. If the p value as reported was less than 0.05 it was declared a significant result and a null hypothesis was rejected.

3.9.2.1 Procedure 1: Wilcoxon's Signed Rank Test

(Intra-Group Tests for Treatment Group and Placebo Group)

Wilcoxon's signed rank test was conducted based on readings from the Sleep Diary (comparing net gains in hours slept per week and total hours of sleep per week), SII and DBAS. It tested for a significant difference in population means between readings within the Treatment Group and the Placebo Group.

(i) Hypothesis testing

The null hypothesis H_0 , states that there is no significant difference between the three consults being compared at the $\alpha = 0.05$ level of significance. The alternative hypothesis H_1 , states that there is a significant difference between the three visits being compared.

(ii) Decision rule

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

3.9.2.2 Procedure 2: Kruskal-Wallis Test

(Inter-Group Tests between both Groups)

The inter-group analysis was done using the Kruskal-Wallis non-parametric analysis of variance (ANOVA) method. The Treatment and Placebo Groups were compared to each other (using Sleep Diary readings) with regards to a comparison of net gains in hours slept and comparison using total hours of sleep.

The two groups were compared to each other (using SII readings) with regards to analysis of each question during all consults. Inter-group analysis of DBAS readings was also conducted.

(i) Hypothesis testing

The null hypothesis H_0 , states that there is no significant difference between the three consults being compared at the $\alpha = 0.05$ level of significance. The alternative hypothesis H_1 , states that there is a significant difference between the three visits being compared.

(ii) Decision rule

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

3.9.2.3 Procedure 3: Comparison using bar charts

Analytical findings were summarized in visual form by using means to construct bar charts to compare readings of Treatment and Placebo Group with respect to scores given for each measurement tool. Bar charts were placed after the appropriate tables.

CHAPTER 4

RESULTS

4.1 CRITERIA FOR ADMISSIBILITY OF THE DATA

Only data collected from this trial (as discussed in Chapter 3) was used to for statistical analysis.

KEY:

W1: week one

W2: week two

W3: week three

W4: week four

C1: Consult one

FU1: Follow-Up one

FU2: Follow-Up two

Q1,2,3 etc,: Question one, two, three

*: significant values

Diff: Difference

4.2 DEMOGRAPHIC DATA

4.2.1 GENDER

There were 30 participants in the study, consisting of 19 males (63%) and 11 females (37%) (see Figure 4.1).

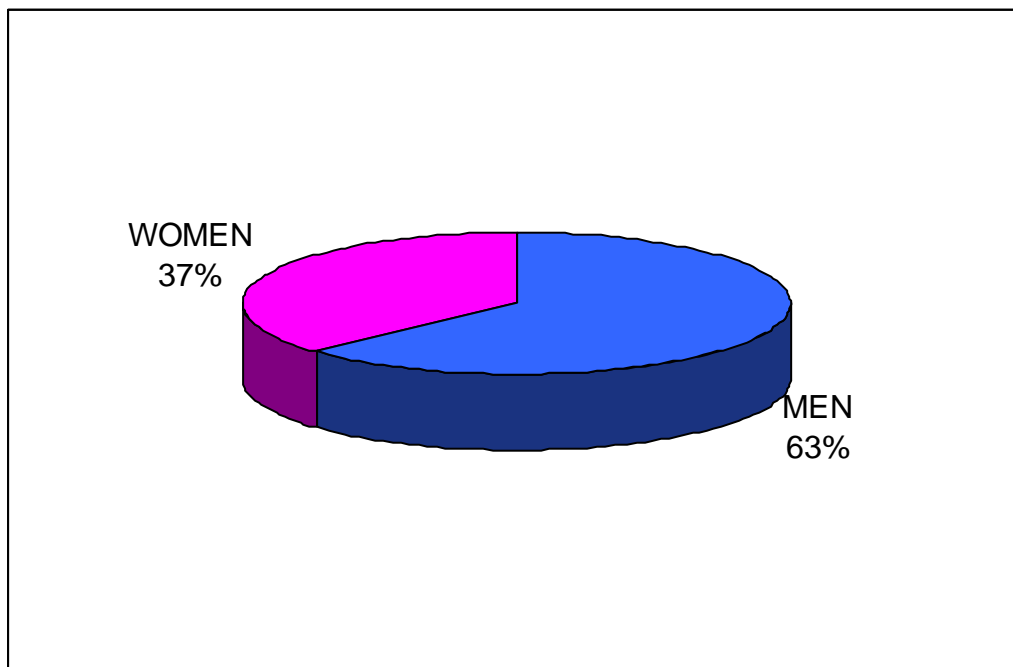


Figure 4.1 Pie chart: Percentage of Genders

4.2.2 AGE

The study consisted of participants between 18 and 70 years of age. There were 10 participants (33%) between 18 – 30 years old and 2 participants (7%) between the ages of 31 and 40 years. 15 Participants (50%) were between 41 - 50 years of age and 3 participants (10%) were between 51 – 60 years old. None of the participants were between 61 and 70 years of age. (see Figure 4.2)

See Figure 4.2 for a graphical representation of the age distribution.

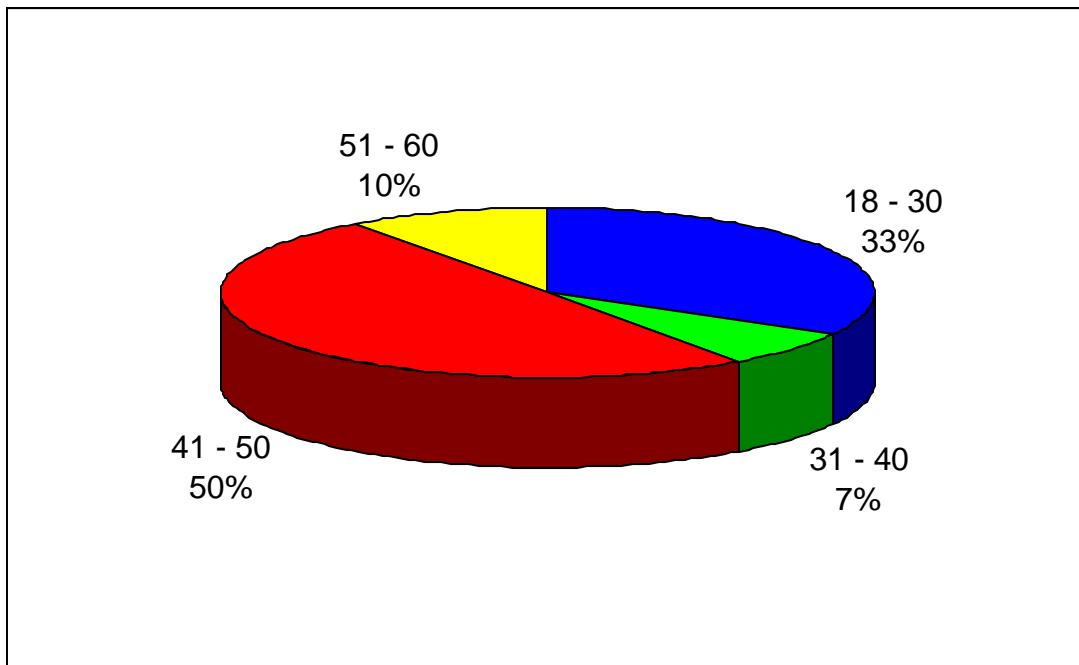


Figure 4.2 Pie chart: Percentage of age groups

4.3 PROCEDURE 1 (INTRA-GROUP): WILCOXON SIGNED RANKS TEST

4.3.1 SLEEP DIARY (Appendix A)

Table 4.1 Comparison of total hours of sleep per week – Sleep Diary

GROUP	W2 – W1 (baseline)	W3 - W1	W4 – W1	W3 – W2	W4 – W3	W4 – W2
Treatment (p value)	.001*	.001*	.002*	.209	.278	.028*
Placebo (p value)	.659	.679	.179	.604	.649	.319

Table 4.1 reveals the following:

Treatment Group: There were significant differences between baseline and weeks 2, 3 and 4 as well as between weeks 2 and 4.

Placebo Group: There were no significant differences between any of the weeks ($p > 0.05$).

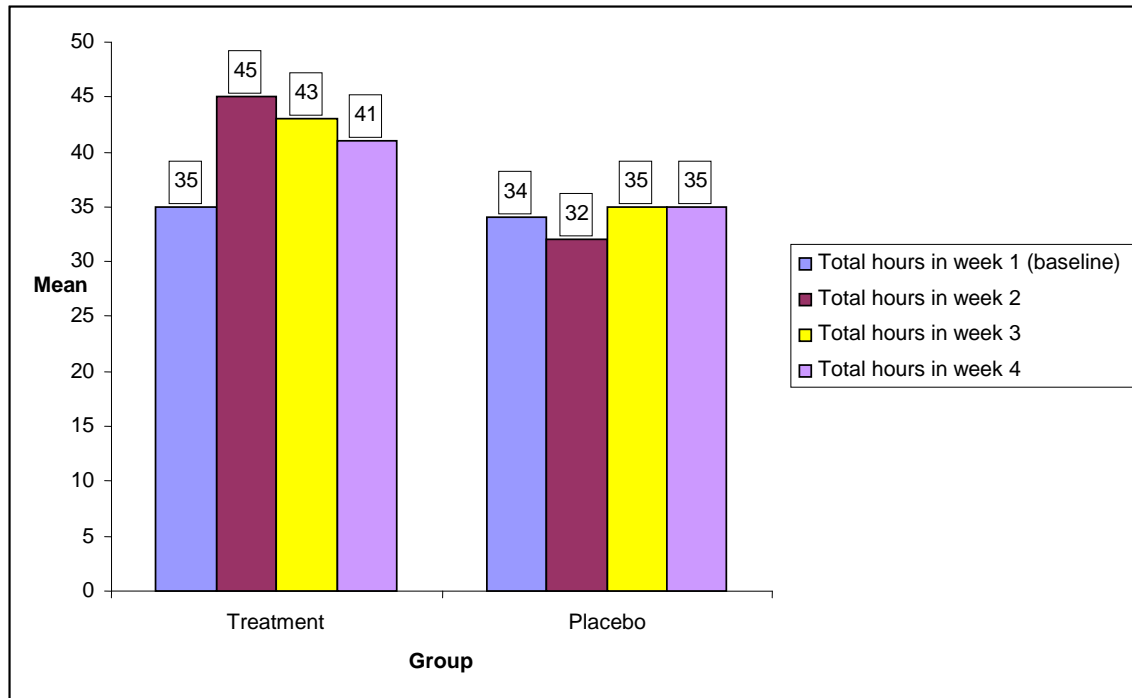


Figure 4.3 Bar chart: Total hours slept per week (Sleep Diary)

Figure 4.3 reveals that baseline values of the total hours slept per week was similar between the 2 groups. The Treatment Group demonstrated a marked increase in total hours slept per week whereas the Placebo Group did not.

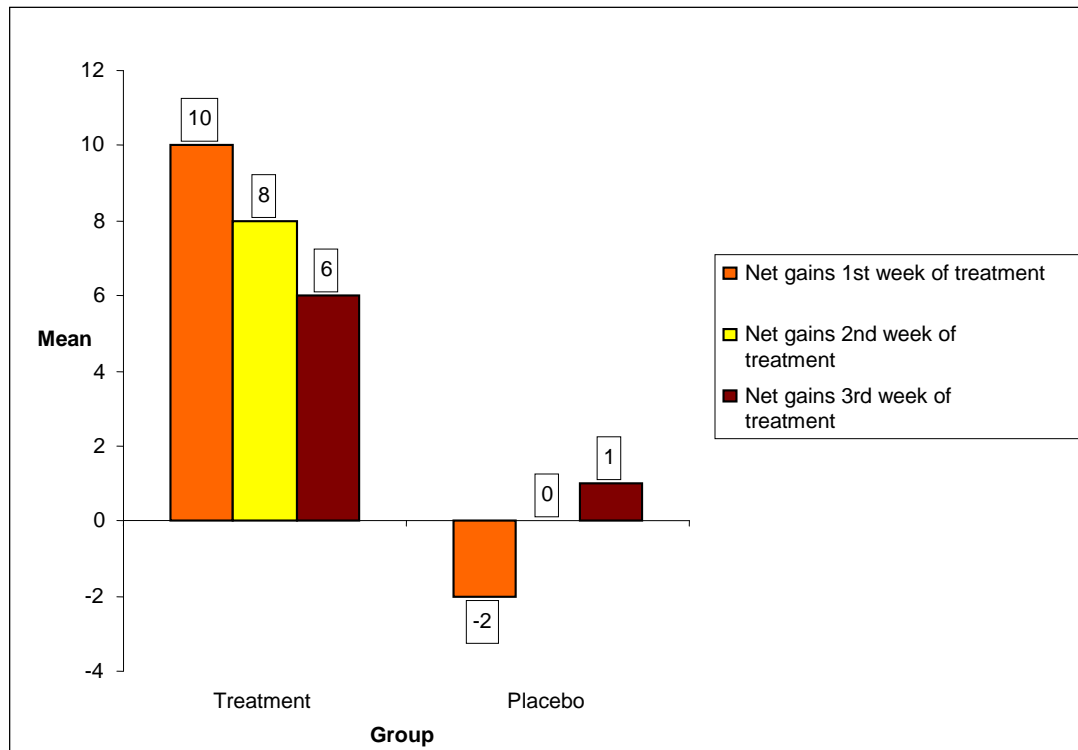


Figure 4.4 Bar chart: Comparison of net gains (means) in hours slept per Week (Sleep Diary)

Figure 4.4 reveals the following:

Treatment Group: The average hours slept per week increased by 10 hours within the first week of treatment. There was a decrease to 8 hours then 6 hours within weeks 3 and 4 respectively.

Placebo Group: There was an average net loss of 2 hours of sleep within the first week of treatment. In the 3rd week there was a return to baseline reading. There was an average gain of 1 hour by the 3rd measurement.

4.3.2 SLEEP IMPAIRMENT INDEX (Appendix B)

Table 4.2 Comparisons between baseline and Follow-Up 1 (FU1) - SII

Group	Q1a	Q1b	Q1c	Q2	Q3	Q4	Q5	Q6a	Q6b	Q6c	Q6d
Treatment (p value)	.006*	.002*	.130	.048*	.006*	.038*	.005*	.003*	.046*	.143	.046*
Placebo (p value)	.680	.453	1.00	.141	.234	.527	.854	.317	1.000	.129	.132

Table 4.2 reveals the following:

Treatment Group: Within the first 2 weeks of the trial, there were significant differences ($p < 0.05$) for Questions 1a, 1b, 2, 3, 4, 5, 6a, 6b and 6d. (9 of 11 variables).

Placebo Group: There was no significant differences within the first 2 weeks ($p > 0.05$).

Table 4.3 Comparisons between Follow-Up 1 (FU1) and Follow-Up 2 (FU2) – SII

Group	Q1a	Q1b	Q1c	Q2	Q3	Q4	Q5	Q6a	Q6b	Q6c	Q6d
Treatment (p value)	.003*	.002*	.003*	.001*	.001*	.012*	.003*	.002*	.006*	.016*	.014*
Placebo (p value)	.034*	.334	.236	.180	.480	.739	.257	.059*	.705	.157	1.000

Table 4.3 reveals the following:

Treatment Group: There were significant differences ($p < 0.05$) in all questions.

Placebo Group: There were significant differences ($p < 0.05$) in Questions 1a and 6a only (i.e. 2 of 11 variables).

Table 4.4 Comparisons between baseline and FU2 - SII

Group	Q1a	Q1b	Q1c	Q2	Q3	Q4	Q5	Q6a	Q6b	Q6c	Q6d
Treatment (p value)	.001*	.001*	.002*	.002*	.001*	.003*	.002*	.001*	.004*	.003*	.006*
Placebo (p value)	.157	.288	.414	.141	.607	.679	.518	.726	.739	.1000	.132

Table 4.4 reveals the following:

Treatment Group: There were significant differences ($p < 0.05$) in every question (i.e. 11 of 11 variables).

Placebo Group: There was no significant difference in any of the questions ($p > 0.05$).

4.3.3 BAR CHARTS COMPARING MEANS FOR SLEEP IMPAIRMENT INDEX

Figures 4.5 – 4.15 are graphical representations for scores on individual questions of the SII. A decrease in mean scores represents an improvement in the relevant variable.

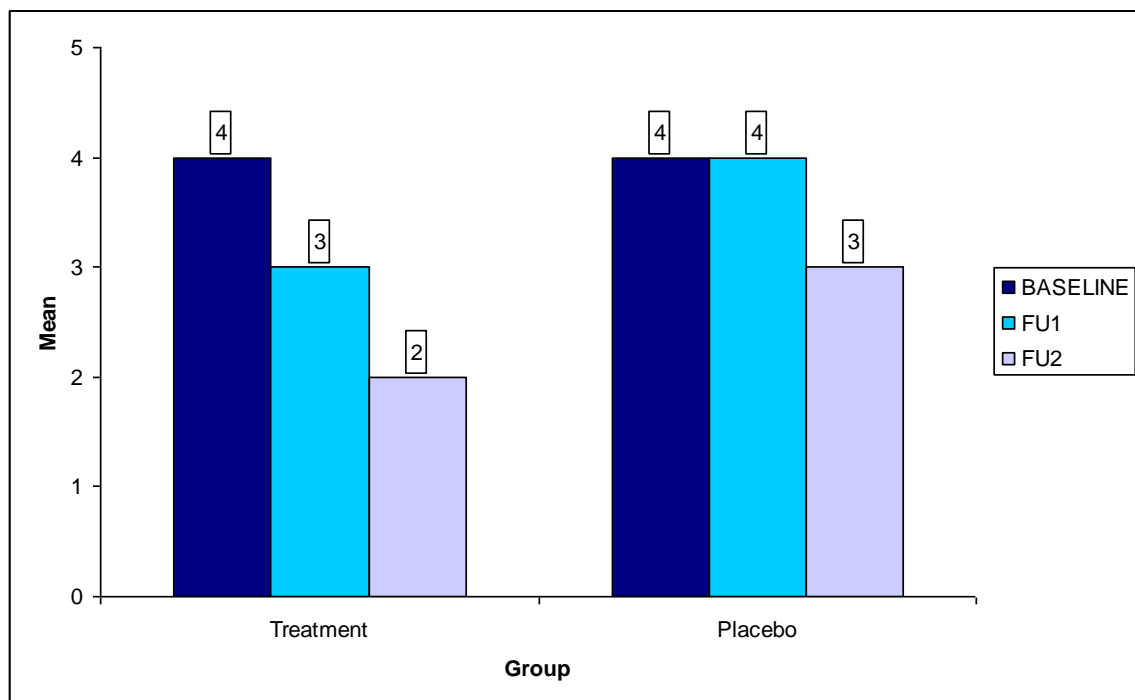


Figure 4.5 Question 1a: *Difficulty falling asleep*

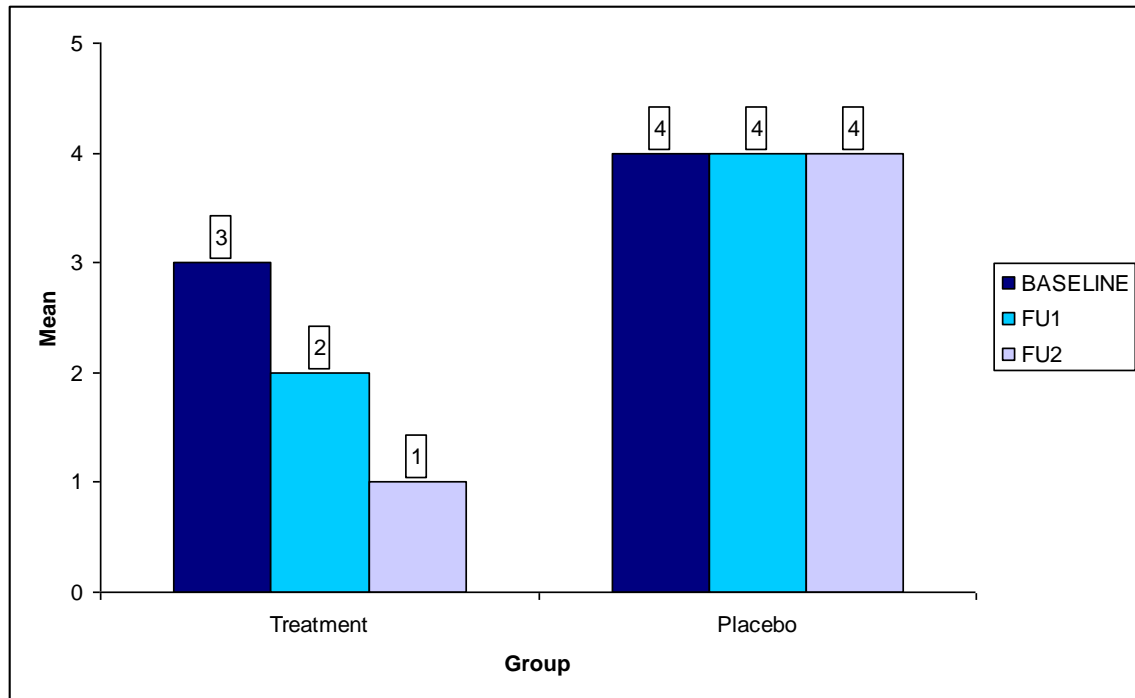


Figure 4.6 Question 1b: *Difficulty staying asleep*

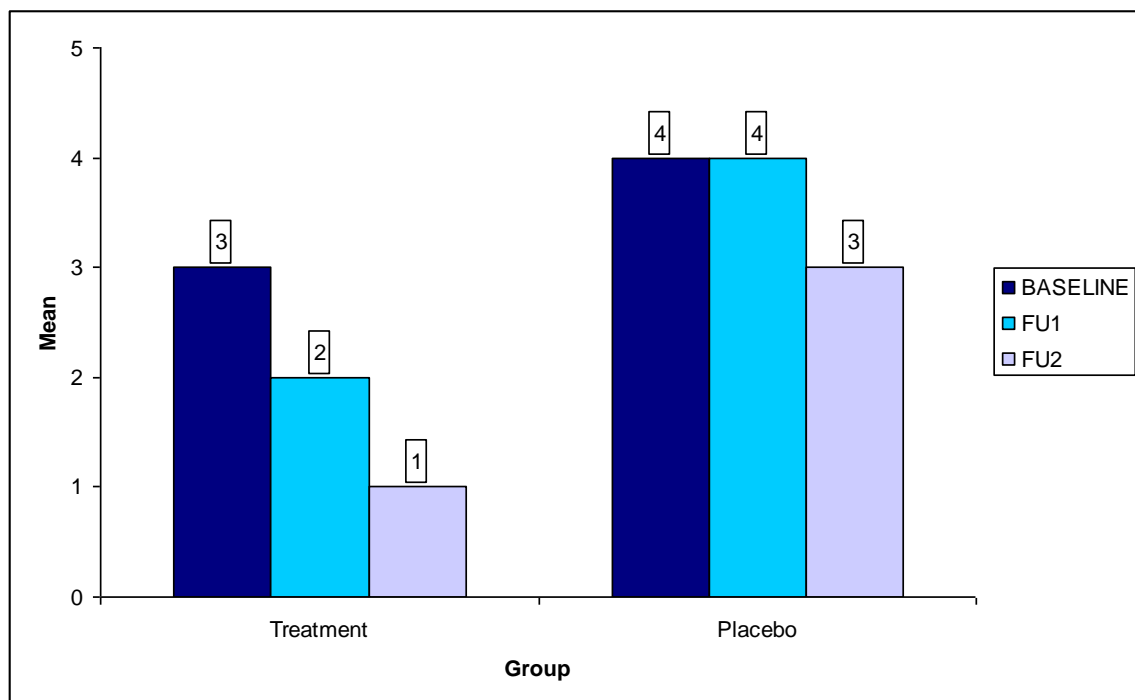


Figure 4.7 Question 1c: *Problems waking up too early*

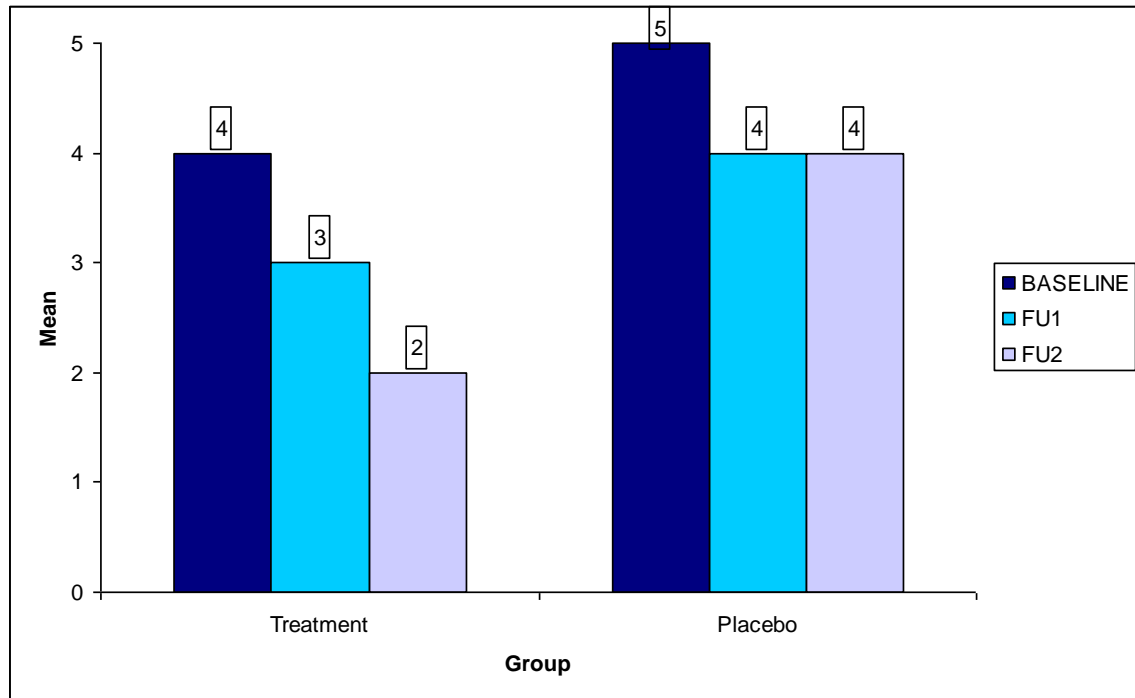


Figure 4.8 Question 2: *How dissatisfied are you with your current sleep pattern?*

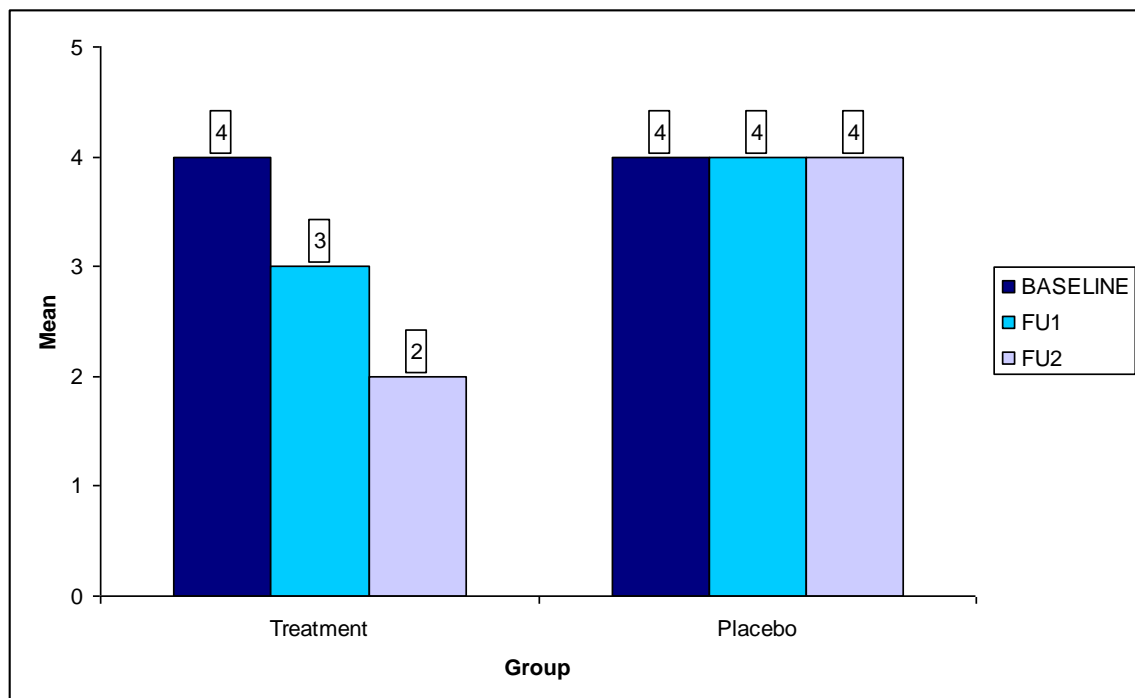


Figure 4.9 Question 3: *To what extent do you consider your sleep problem to interfere with your daily functioning (e.g. daytime fatigue, ability to function at work/daily chores, concentration, memory, etc.)?*

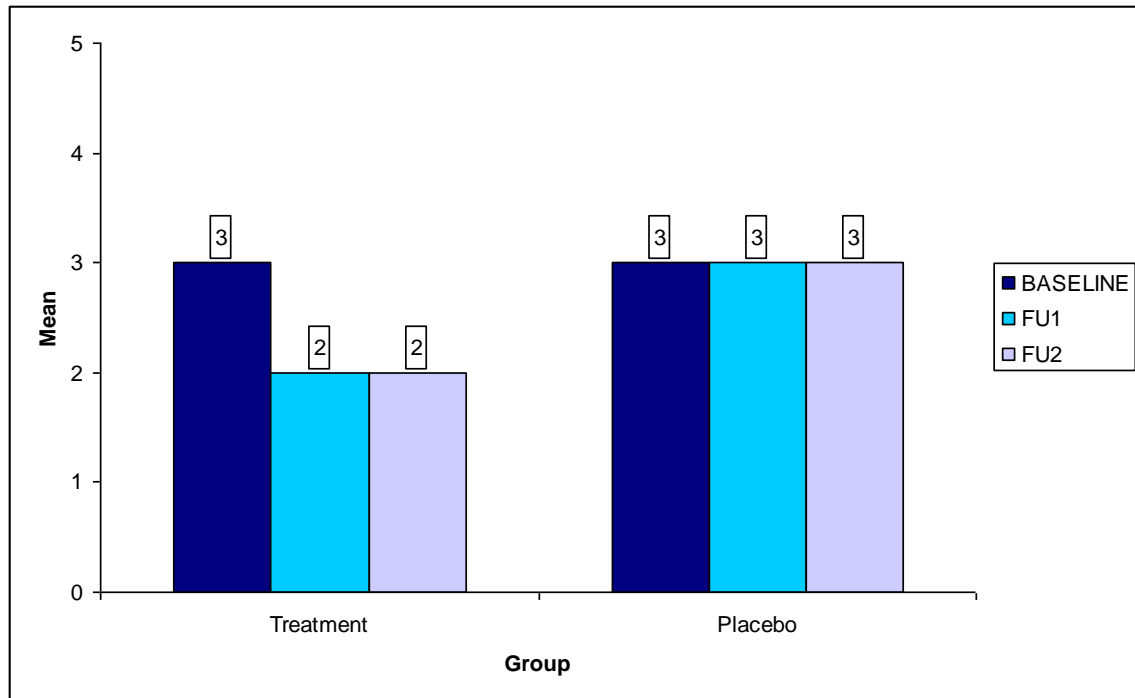


Figure 4.10 Question 4: *How noticeable to others do you think your sleeping problem is in terms of impairing the quality of your life?*

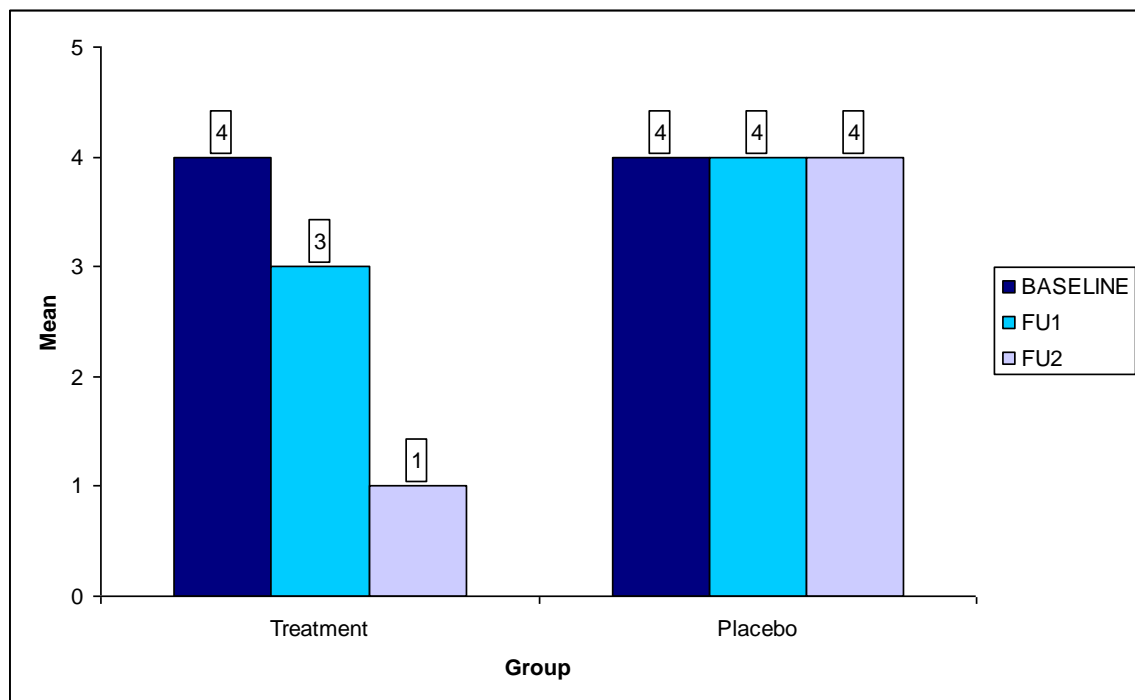


Figure 4.11 Question 5: *How concerned are you about your current sleep problem?*

Question 6: To what extent do you believe the following factors are contributing to your sleep problem?

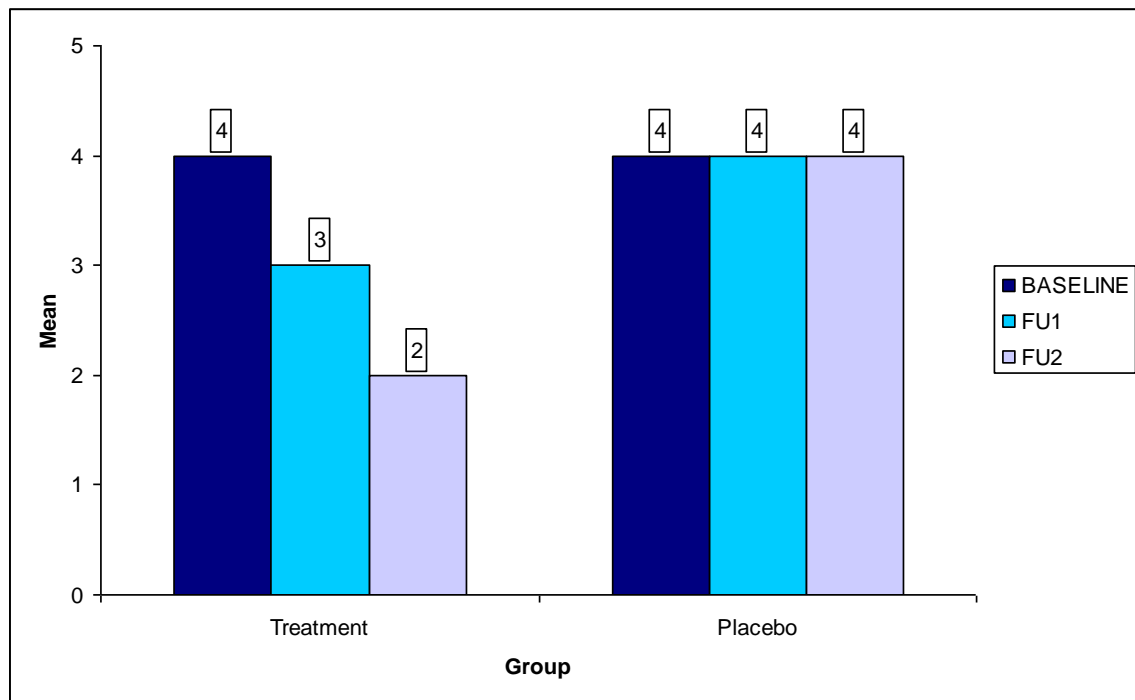


Figure 4.12 Question 6 a: Cognitive disturbances (racing thoughts at night)

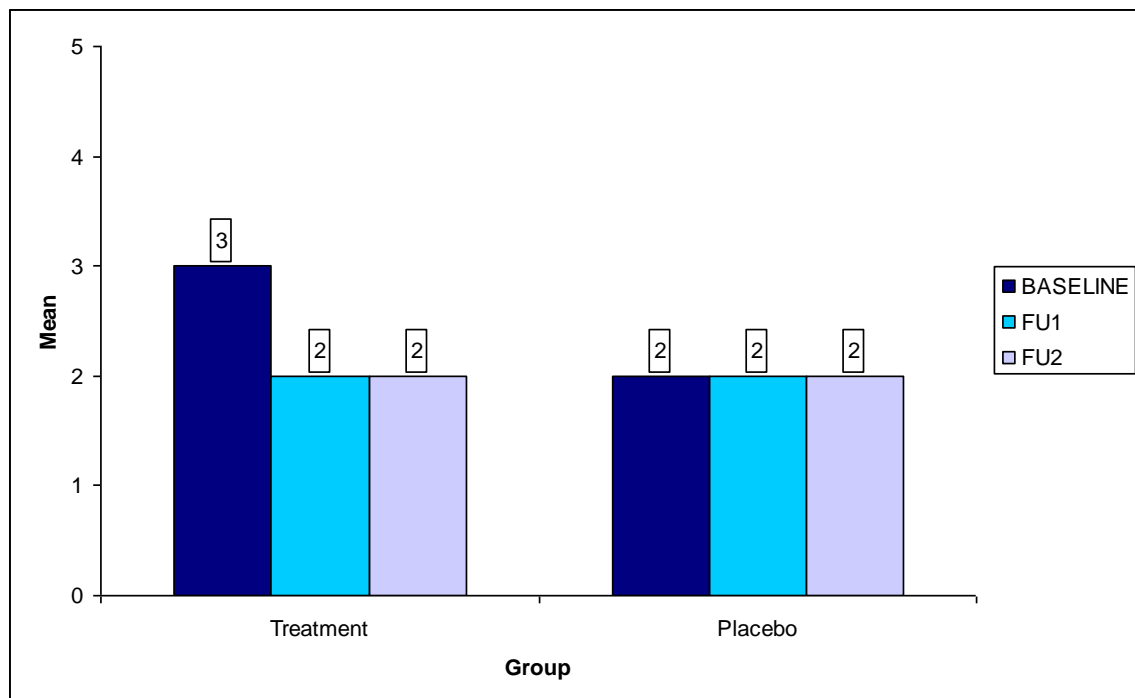


Figure 4.13 Question 6 b: Somatic disturbances (muscular tension, pain)

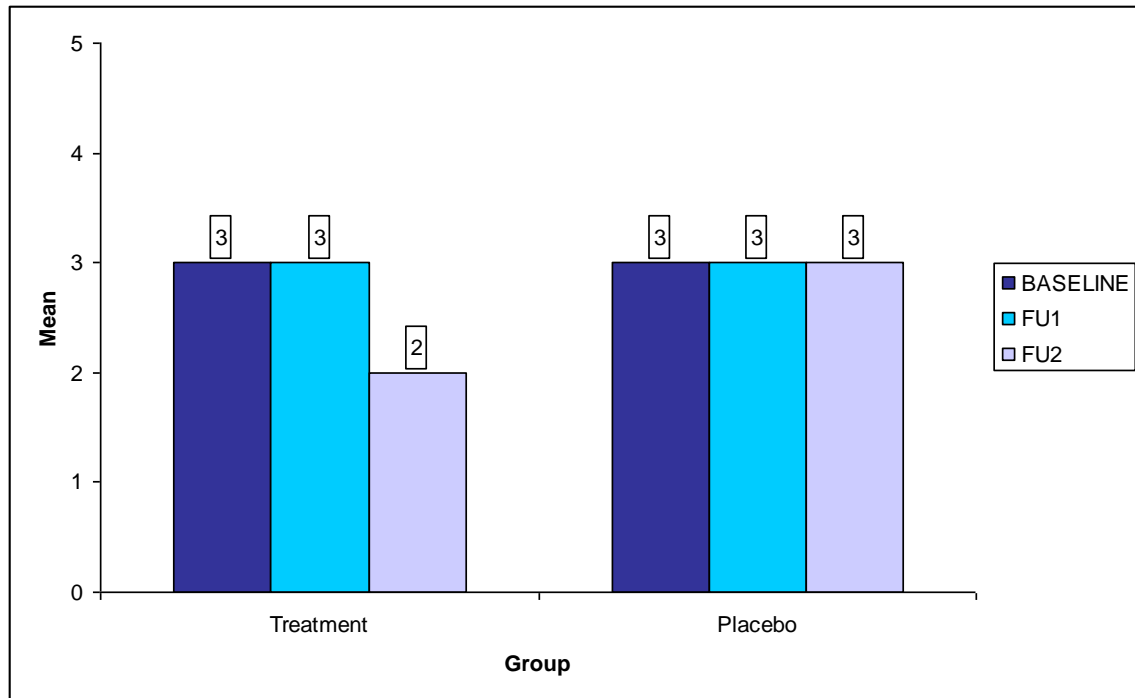


Figure 4.14 Question 6 c: *Bad sleeping habits*

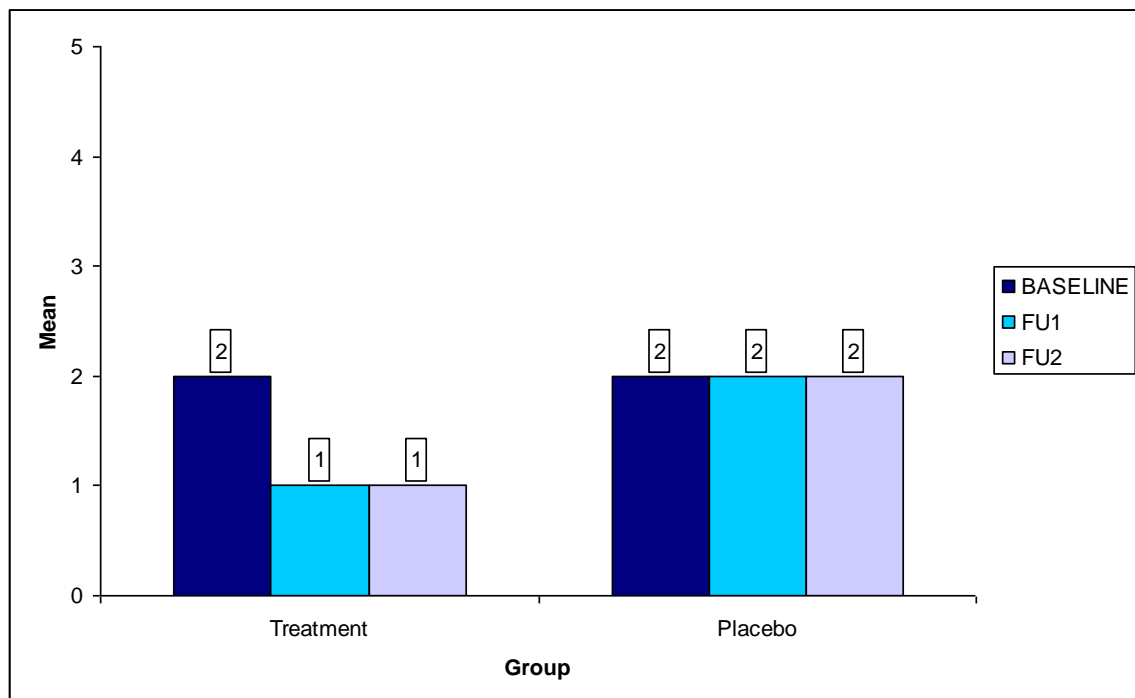


Figure 4.15 Question 6 d: *Natural aging process*

4.3.4 DYSFUNCTIONAL BELIEFS AND ATTITUDES ABOUT SLEEP SCALE (DBAS) (Appendix C)

Table 4.5 Comparisons between baseline and FU1 - DBAS

Question	Treatment Group (p value)	Placebo Group (p value)
1	0.025*	.726
2	0.358	0.206
3	0.483	0.438
4	0.317	0.557
5	0.038*	0.257
6	0.107	0.304
7	0.170	0.762
8	0.861	0.058*
9	0.480	0.596
10	0.006*	0.109
11	0.058*	0.119
12	1	0.546
13	0.020*.	0.236
14	0.739	0.236
15	0.783	0.099
16	1	0.392
17	0.564	0.685
18	0.914	0.527
19	0.256	0.958
20	0.011*	0.248
21	0.705	0.052*
22	0.033*	0.931
23	0.011*	0.254

24	0.317	1
25	0.609	0.719
26	0.054*	0.903
27	0.680	0.943
28	0.2	0.631
29	0.027*	0.942
30	0.454	0.564
Total:	0.146	0.916

Table 4.5 reveals the following:

Treatment Group: Within the first week of treatment, there were significant differences ($p < 0.05$) in Questions 1, 5, 10, 11, 13, 20, 22, 23, 26 and 29 (10 of 31 variables).

Placebo Group: There were significant differences ($p < 0.05$) in Questions 8 and 21 only (2 of 31 variables).

Table 4.6 Comparisons between FU1 and FU2 – DBAS

Question	Treatment Group (p value)	Placebo Group (p value)
1	0.047*	0.733
2	0.915	0.210
3	0.915	0.047*
4	0.010*	0.608
5	0.026*	0.038*
6	0.271	0.034*
7	0.739	0.157
8	0.018*	0.031*
9	0.025*	0.085
10	0.096	0.150
11	0.063	0.670
12	0.032*	0.016*
13	0.480	0.305
14	0.121	1
15	0.414	0.084
16	0.057*	0.020*
17	0.007*	0.096
18	0.058*	0.336
19	0.046*	0.317
20	0.558	0.032*
21	0.039*	0.429
22	0.145	0.184
23	0.030*	0.142
24	0.023*	0.083
25	0.236	0.121
26	0.257	0.196

27	1	0.157
28	0.317	0.566
29	0.603	0.033*
30	0.149	0.160
Total:	0.005*	0.004*

Table 4.6 reveals the following:

Treatment Group: Within 2 weeks of the second prescription, there were significant differences ($p < 0.05$) in Questions 1, 4, 5, 8, 9, 12, 16, 17, 18, 19, 21, 23, 24 and total scores (14 of 31 variables).

Placebo Group: Within 2 weeks of the second prescription, there were significant differences ($p < 0.05$) in Questions 3, 5, 6, 8, 12, 16, 20, 29 and total scores (9 of 31 variables).

Table 4.7 Comparisons between baseline and FU2 - DBAS

Question	Treatment Group (p value)	Placebo Group (p value)
1	0.004*	0.429
2	0.320	0.070
3	0.603	0.298
4	0.031*	0.351
5	0.006*	0.184
6	0.417	0.565
7	0.070	0.265
8	0.054*	0.757
9	0.066	0.161
10	0.001*	0.004*
11	0.010*	0.026*
12	0.102	0.038*
13	0.026*	1
14	0.121	0.272
15	0.739	0.492
16	0.033*	0.380
17	0.013*	0.655
18	0.281	0.414
19	0.007*	0.631
20	0.020*	0.236
21	0.047*	0.022*
22	0.006*	0.150
23	0.748	0.321
24	0.057*	0.070
25	0.791	0.106
26	0.020*	0.203

27	0.719	0.323
28	0.028*	0.959
29	0.130	0.094
30	0.293	0.068
Total:	0.001*	0.043*

Table 4.7 reveals the following:

Treatment Group: There were significant differences ($p < 0.05$) in Questions 1, 4, 5, 8, 10, 11, 13, 16, 17, 19, 20, 21, 22, 24, 26, 28 and total scores (17 of 31 variables).

Placebo Group: There were significant differences ($p < 0.05$) in Questions 10, 11, 12, 21 and the total scores only (5 of 31 variables).

4.3.5 BAR CHARTS COMPARING MEANS FOR DBAS

Figures 4.16 – 4.45 are graphical representations for scores on individual questions of the DBAS. Figure 4.46 is a graphical representation of the total scores. A decrease in mean scores represents an improvement in the relevant variable.

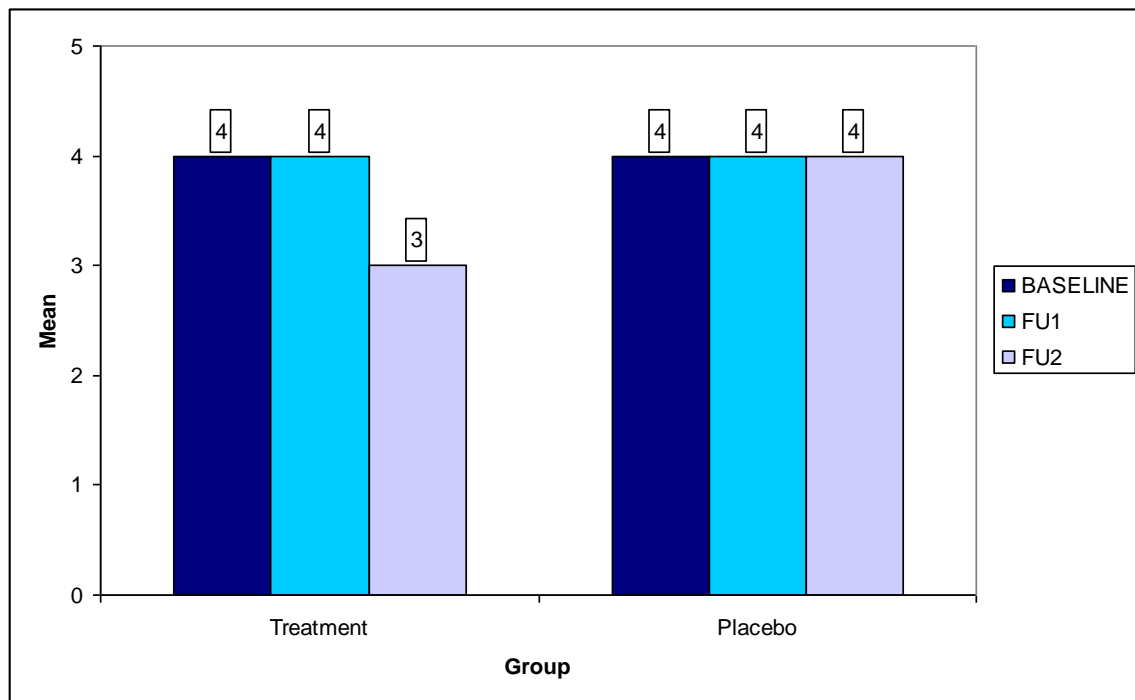


Figure 4.16 Question 1: *I need 8 hours of sleep to feel refreshed and function well during the day*

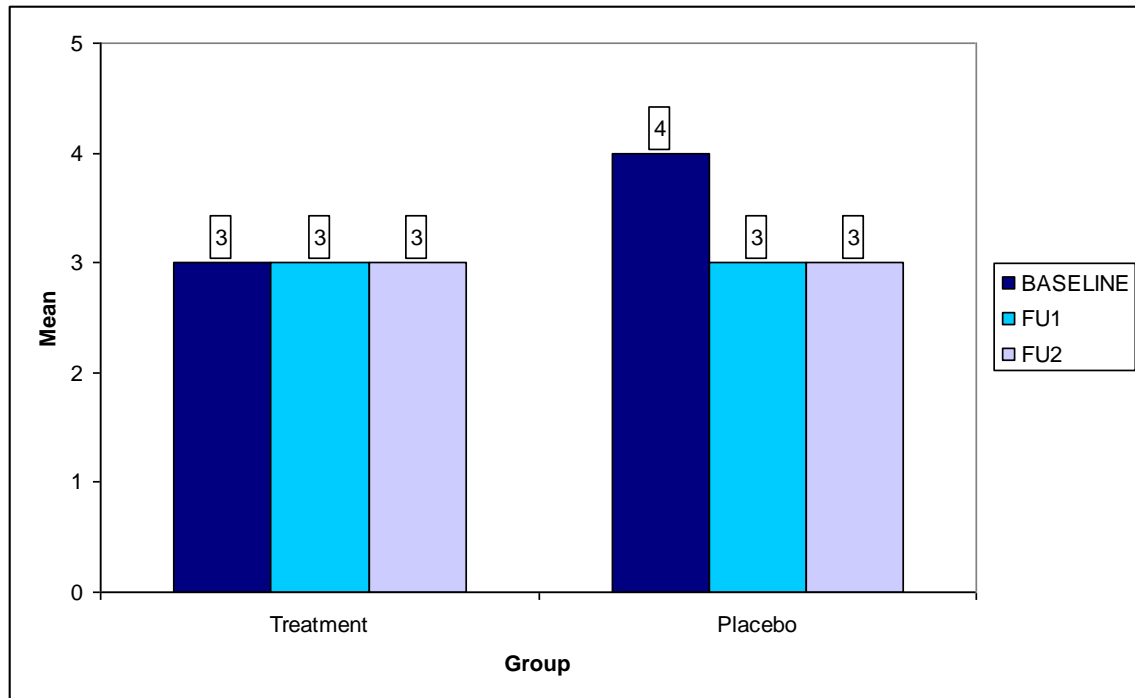


Figure 4.17 Question 2: *When I don't get a proper amount of sleep on a given night, I need to catch up on the next day by napping or on the next night by sleeping longer*

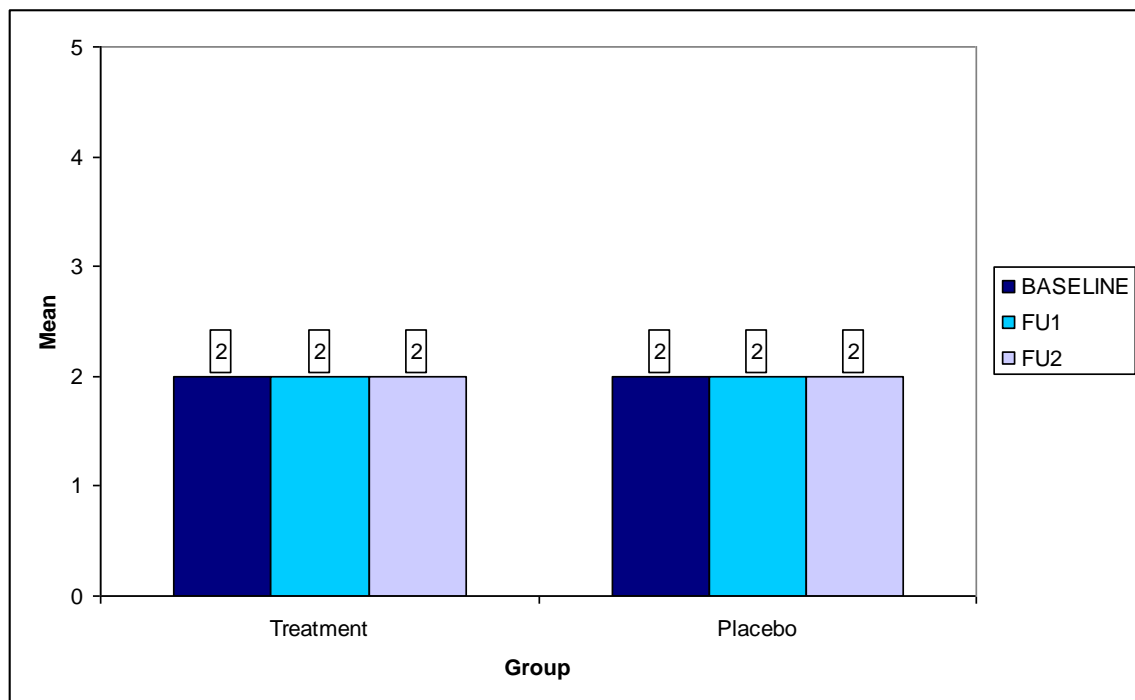


Figure 4.18 Question 3: *Because I am getting older, I need less sleep*

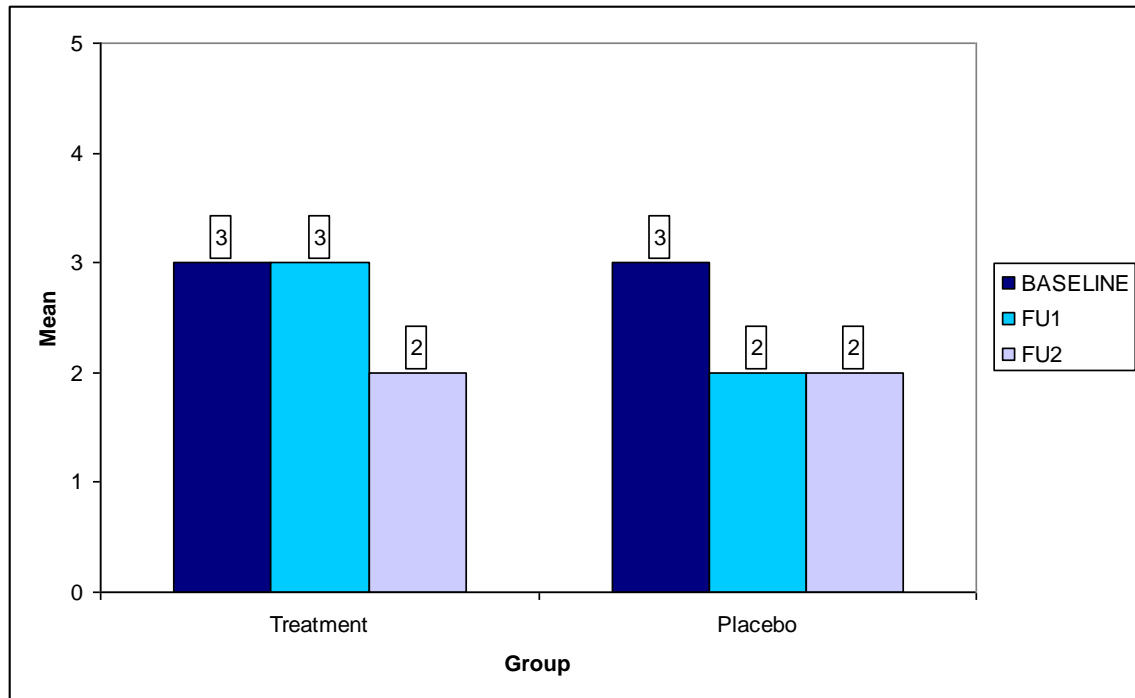


Figure 4.19 Question 4: *I am worried that if I go for one or two nights without sleep, I may have a nervous breakdown*

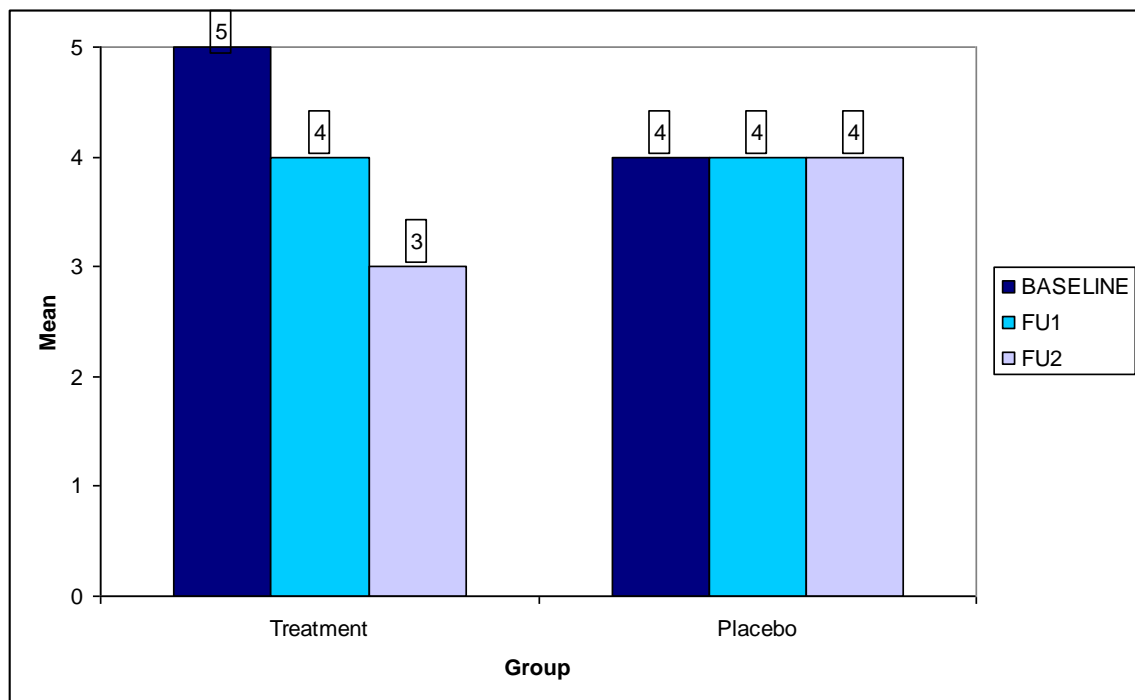


Figure 4.20 Question 5: *I am concerned that chronic insomnia may have serious consequences for my physical health*

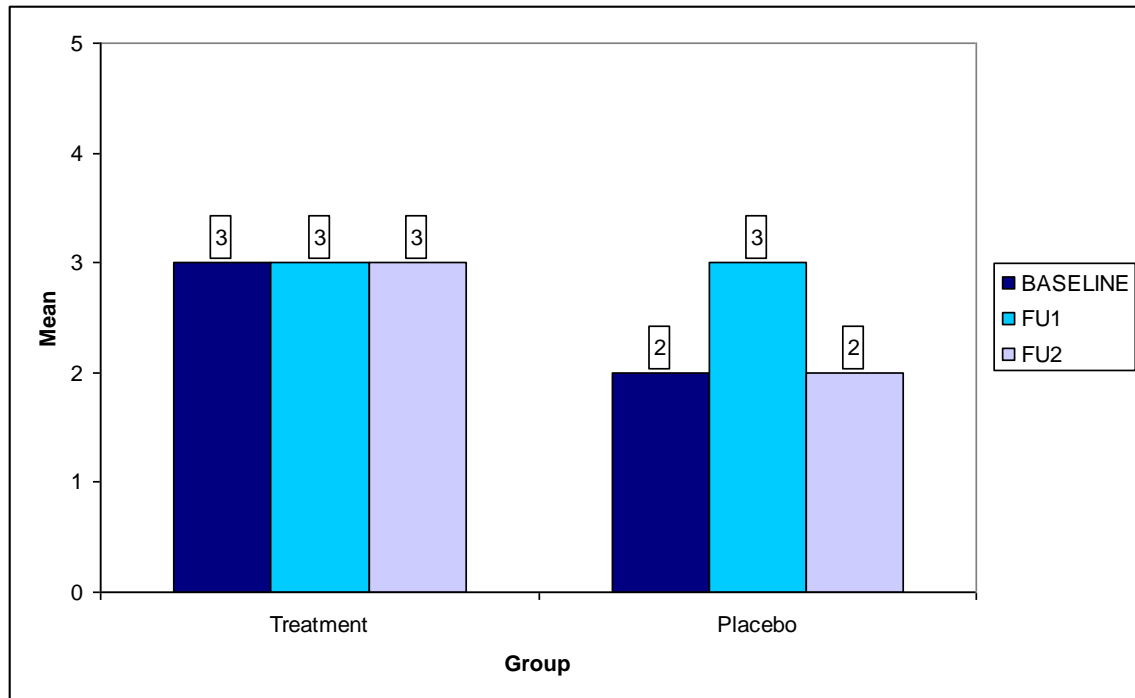


Figure 4.21 Question 6: *By spending more time in bed, I usually get more sleep and feel better the next day*

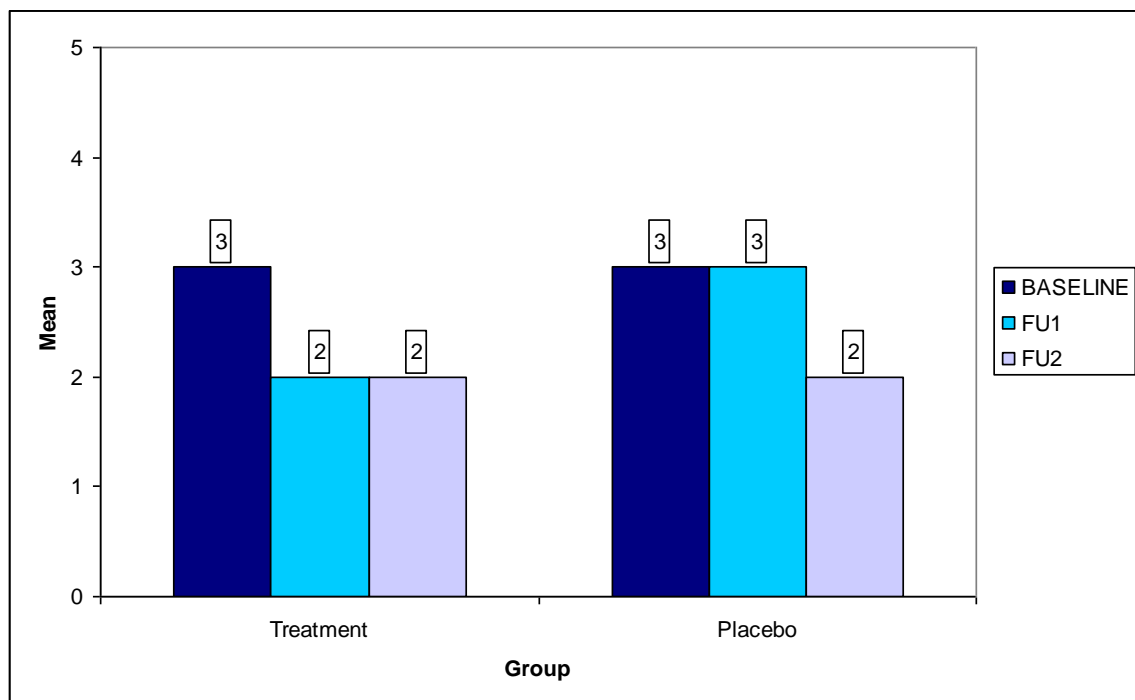


Figure 4.22 Question 7: *When I have trouble getting to sleep, I should stay in bed and try harder*

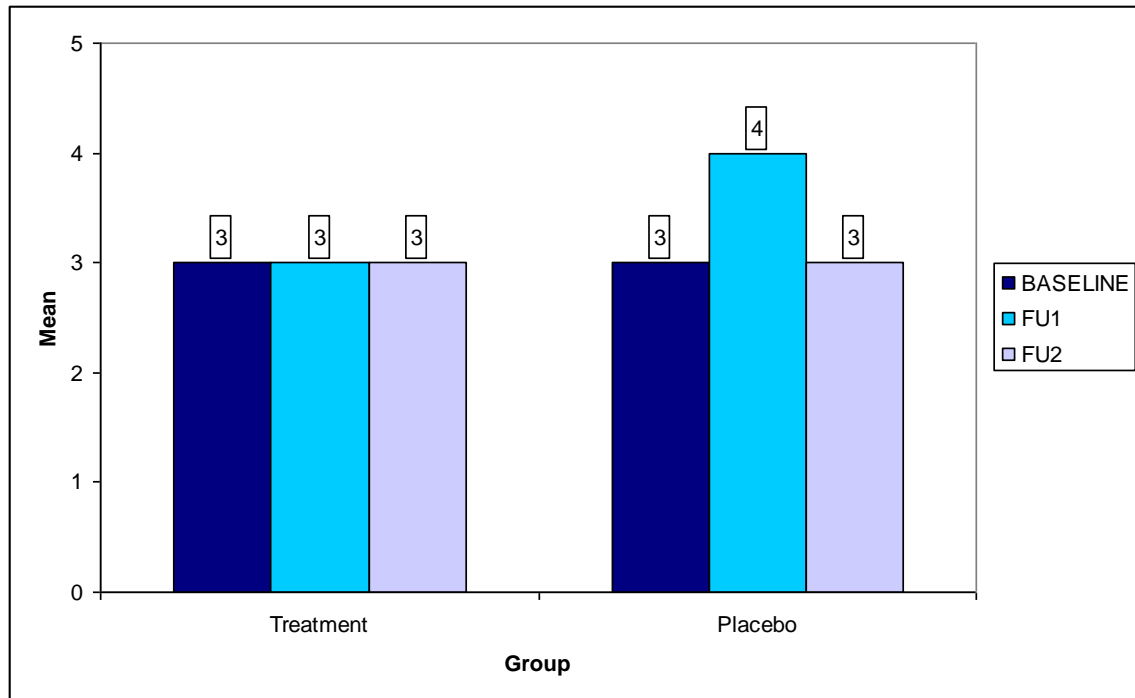


Figure 4.23 Question 8: *I am worried that I may lose control over my abilities to sleep*

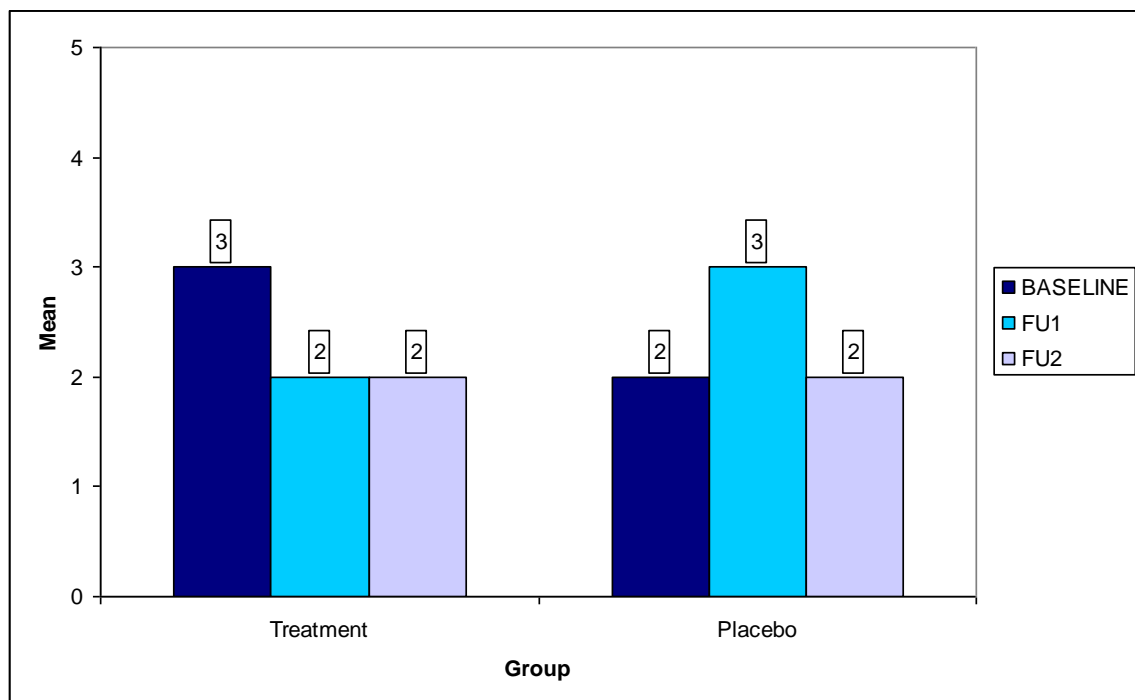


Figure 4.24 Question 9: *Because I am getting older, I should go to bed earlier in the evening*

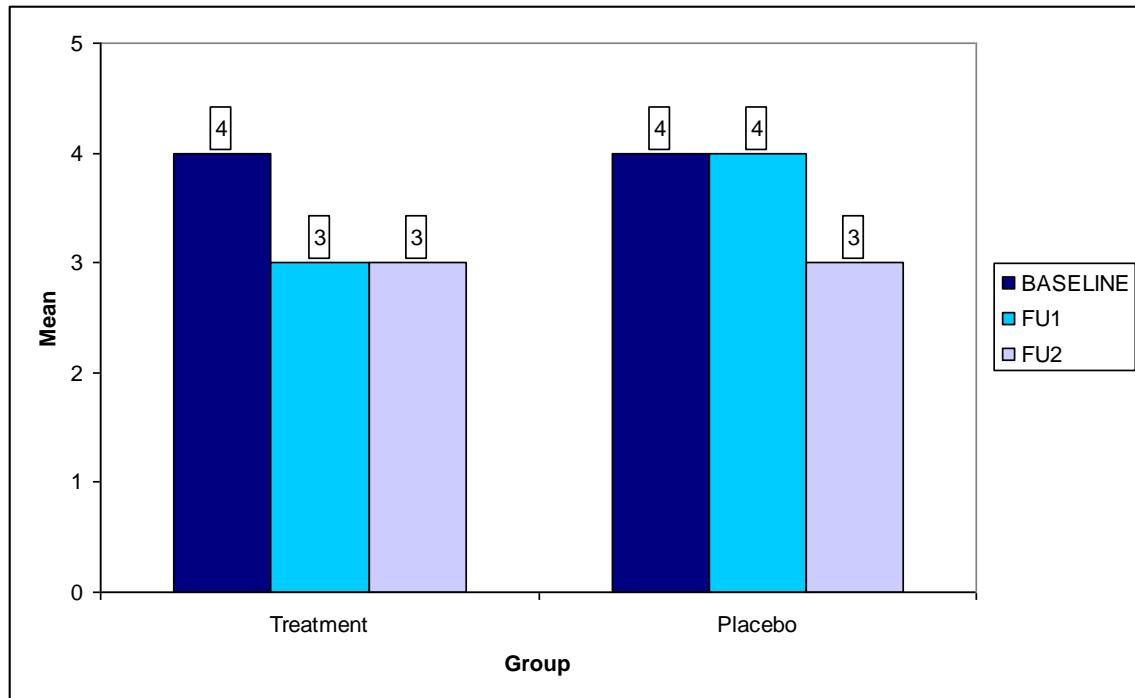


Figure 4.25 Question 10: *After a poor night's sleep, I know that it will interfere with my daily activities on the next day*

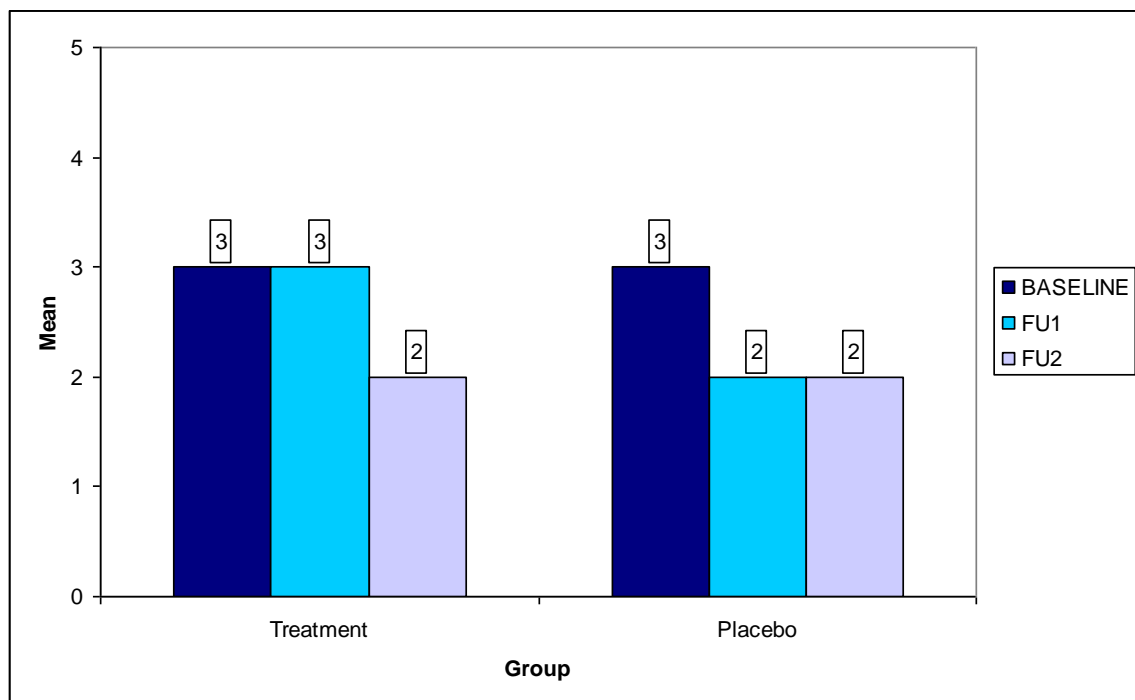


Figure 4.26 Question 11: *In order to be alert and function well during the day, I am better off taking a sleeping pill rather than having a poor night's sleep*

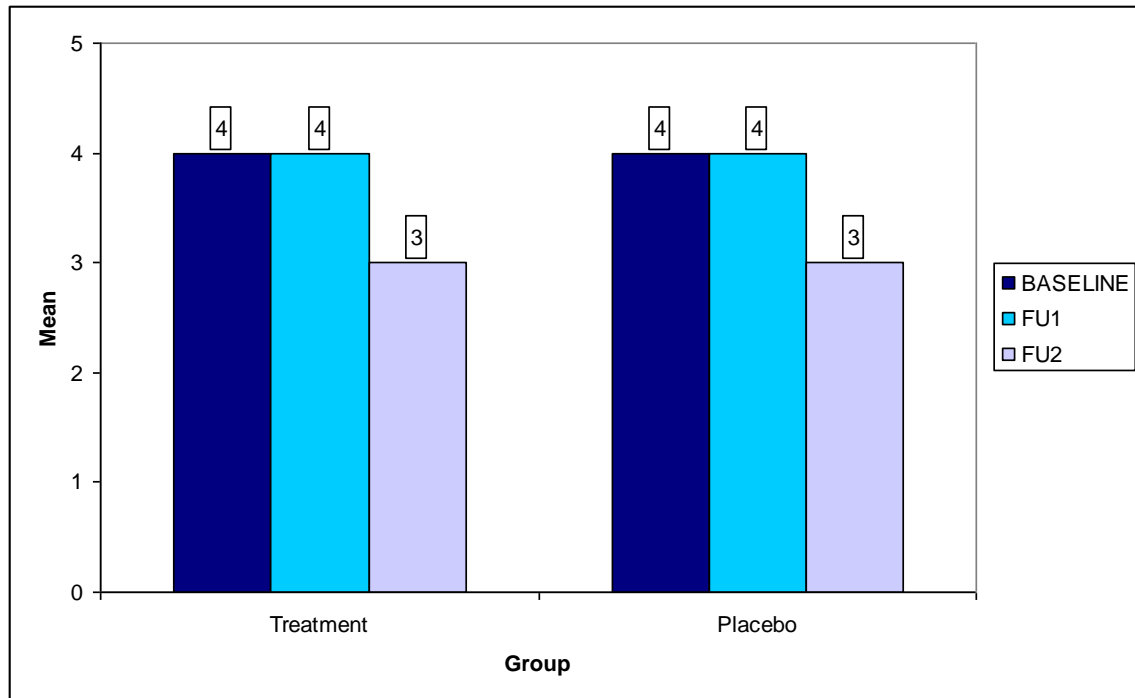


Figure 4.27 Question 12: *When I feel irritable, depressed, or anxious during the day, it is mostly because I did not sleep well the night before*

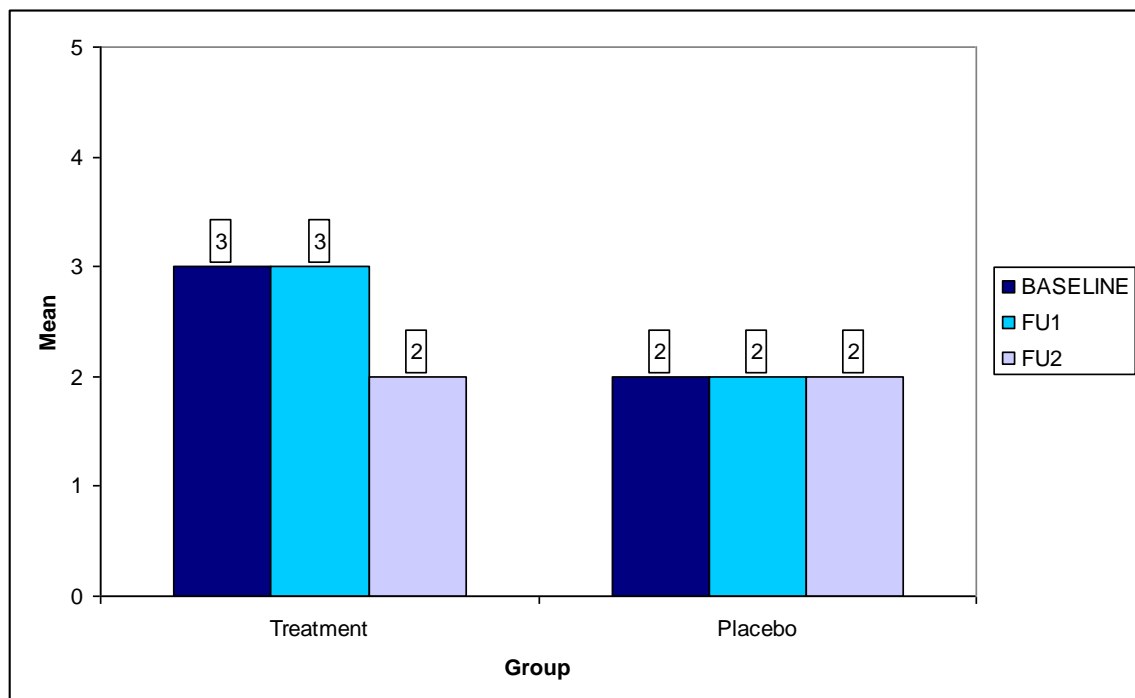


Figure 4.28 Question 13: *Because my bed partner falls asleep as soon as his or her head hits the pillow and stays asleep through the night, I should be able to do so too*

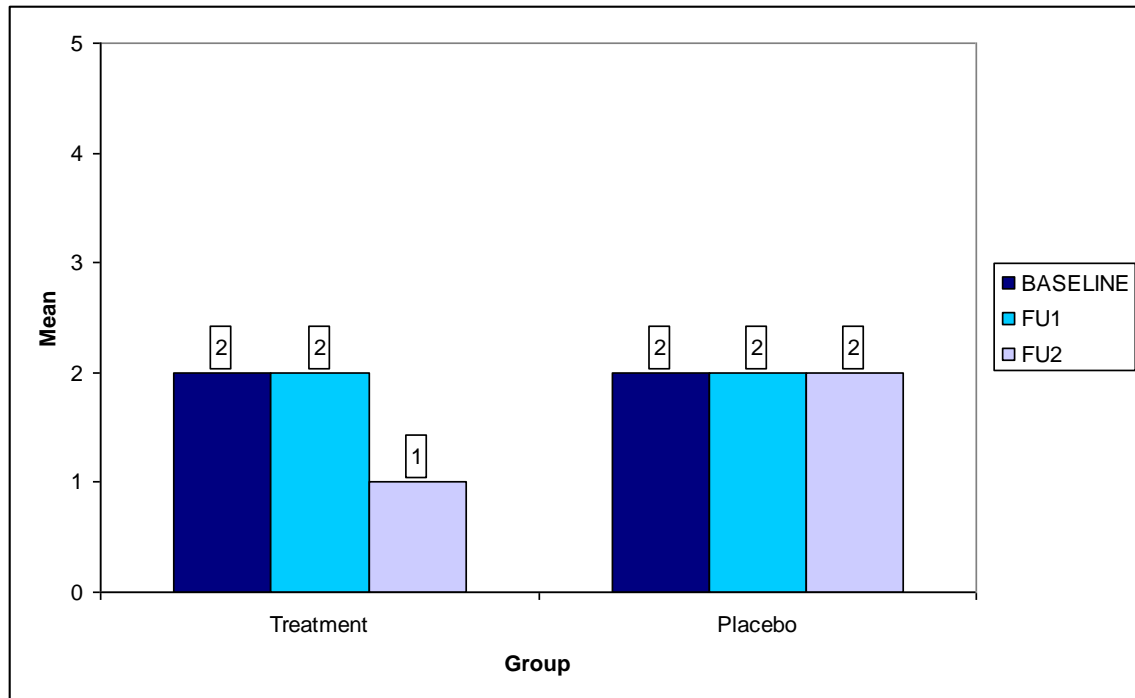


Figure 4.29 Question 14: *I feel that insomnia is basically the result of aging, and there isn't much that can be done about this problem*

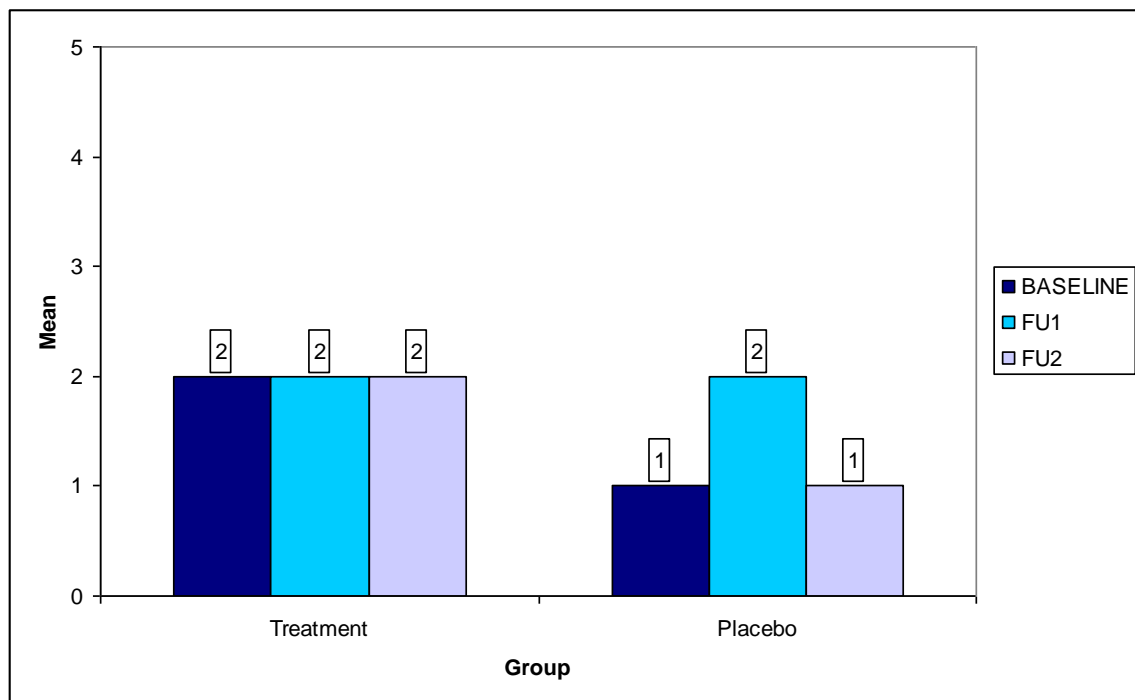


Figure 4.30 Question 15: *I am sometimes afraid of dying in my sleep*

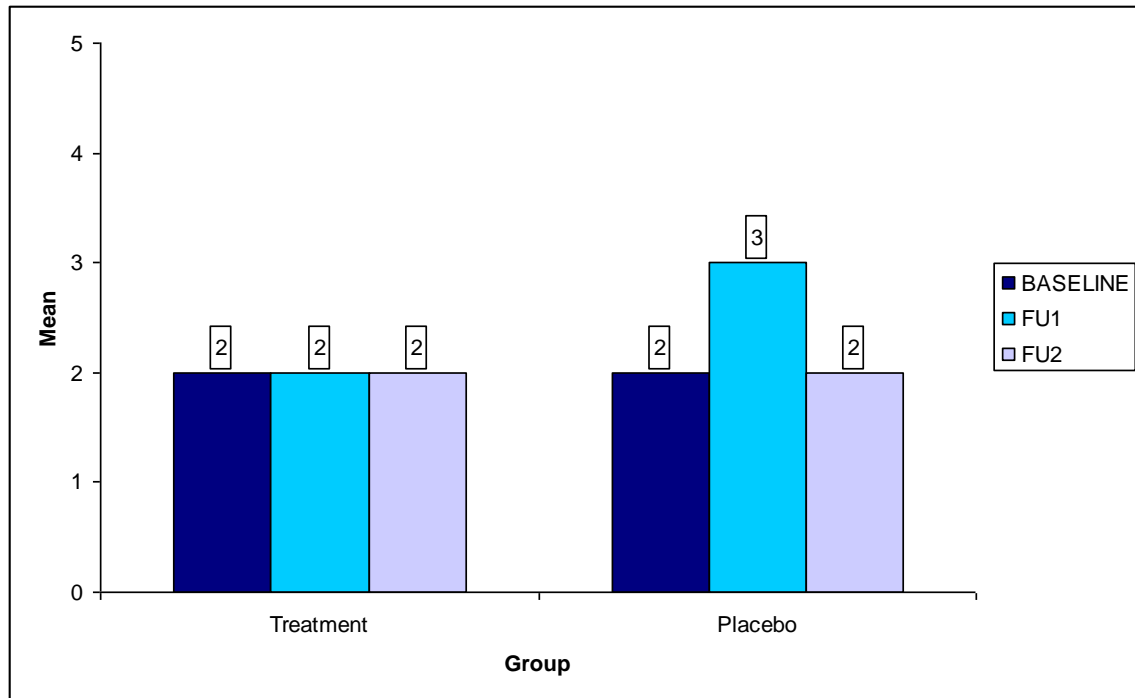


Figure 4.31 Question 16: *When I have a good night's sleep, I know that I will have to pay for it on the following night*

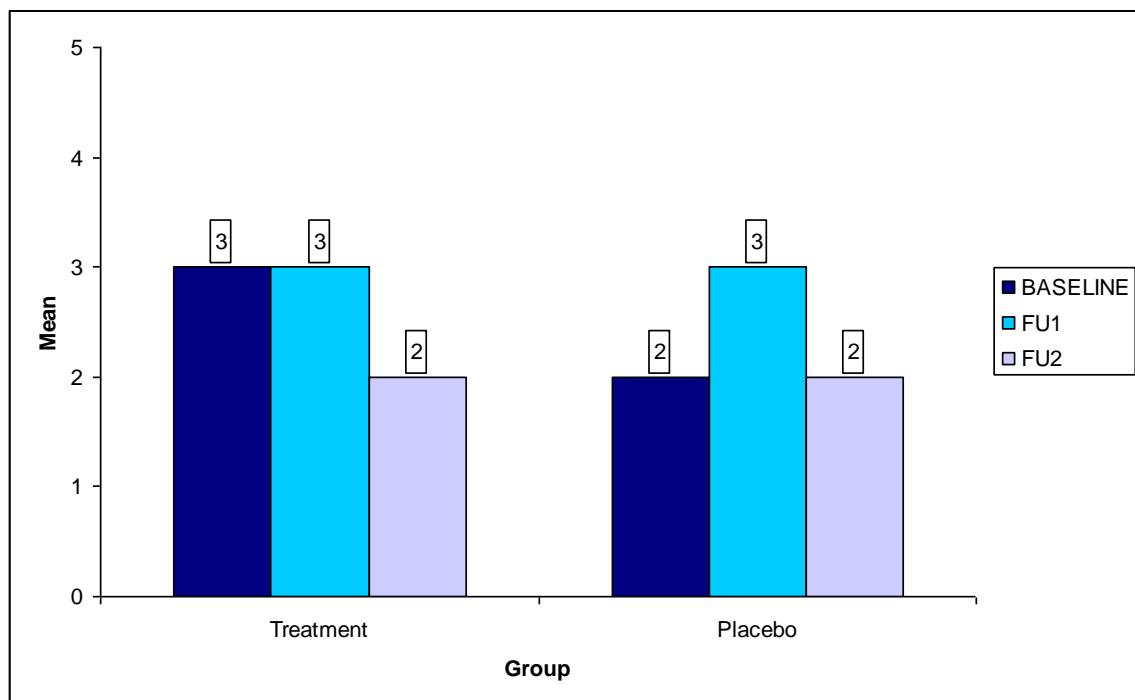


Figure 4.32 Question 17: *When I sleep poorly on one night, I know it will disturb my sleep schedule for the whole week*

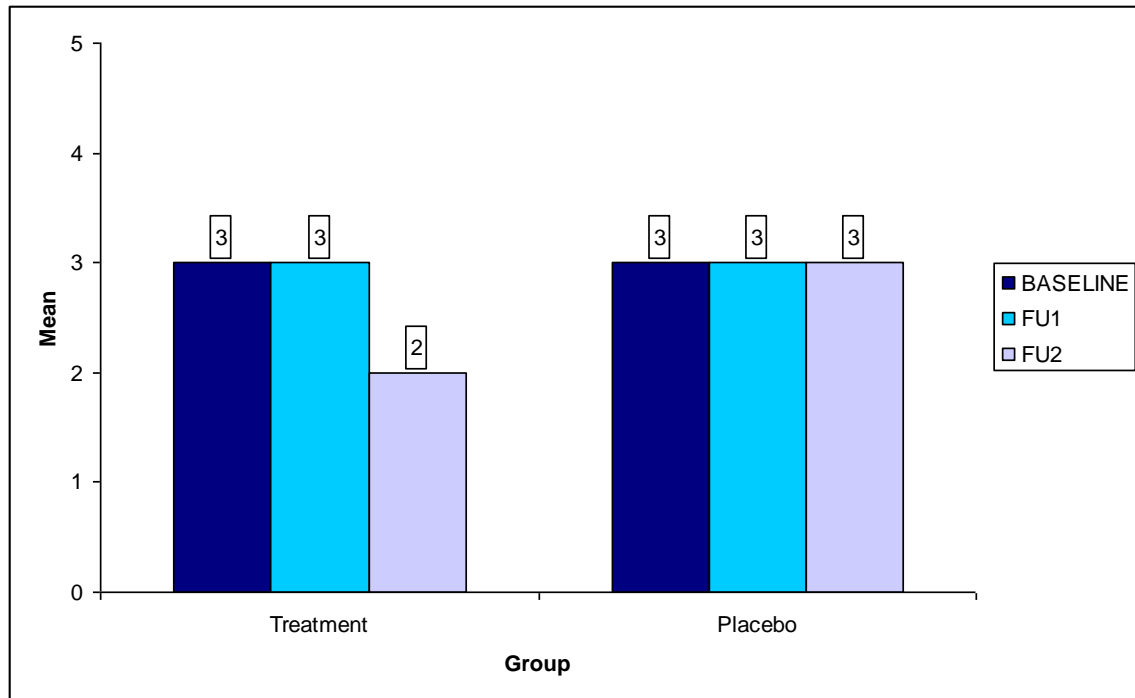


Figure 4.33 Question 18: *Without an adequate night's sleep, I can hardly function the next day*

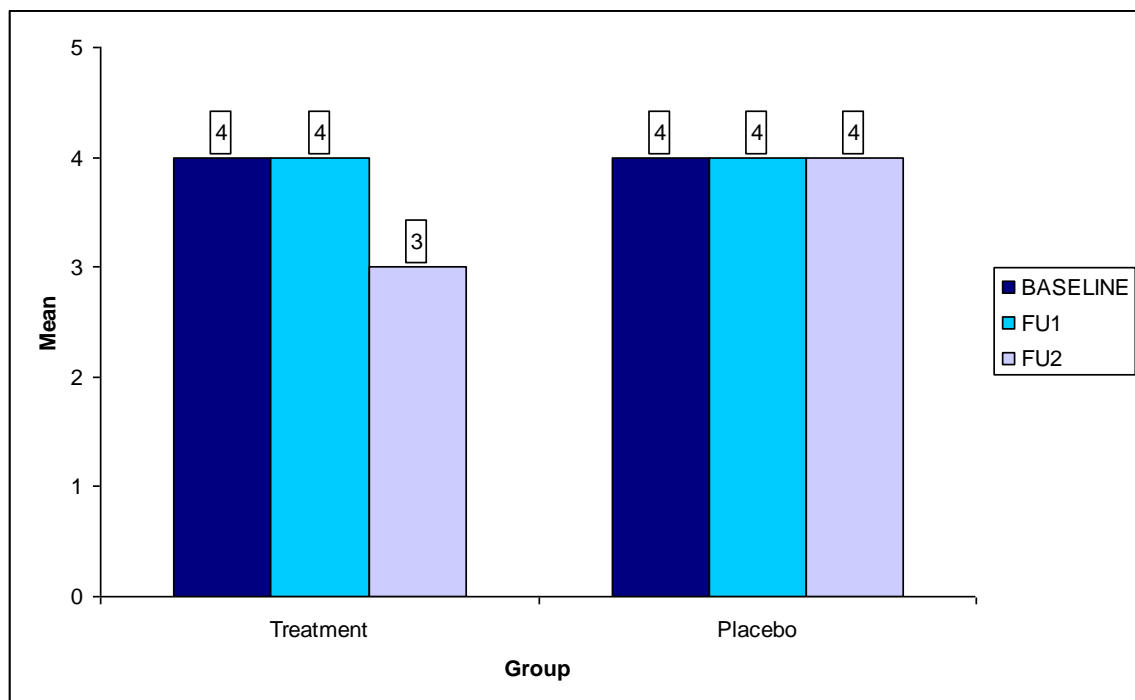


Figure 4.34 Question 19: *I can't ever predict whether I'll have a good or poor night's sleep*

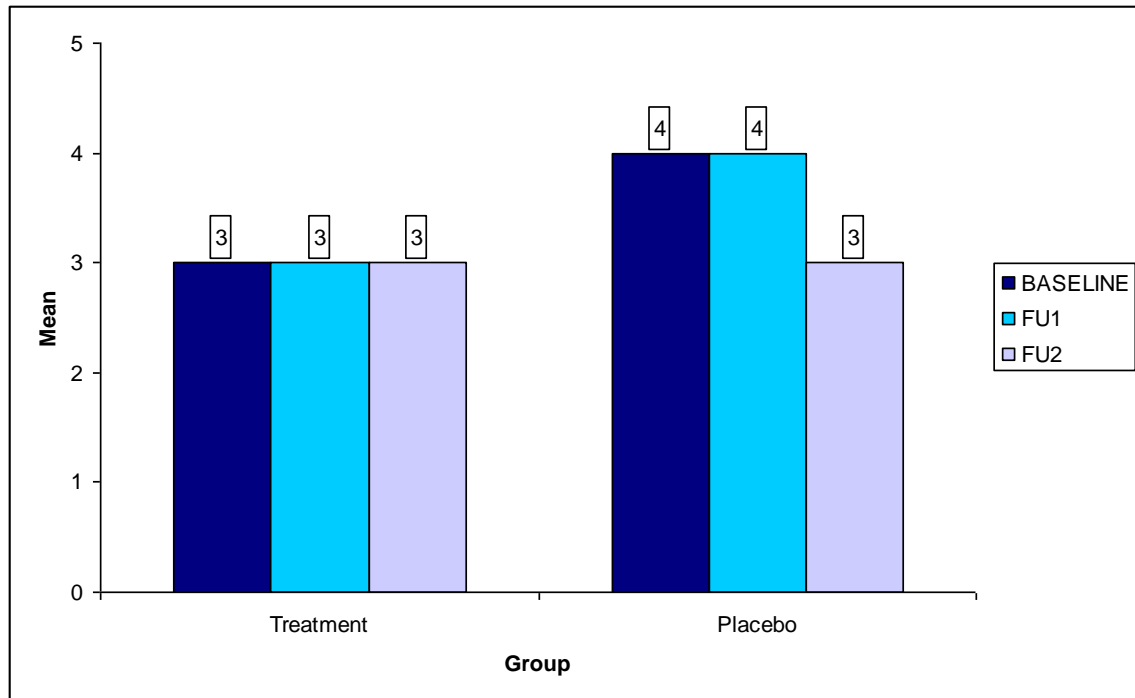


Figure 4.35 Question 20: *I have little ability to manage the negative consequences of disturbed sleep*

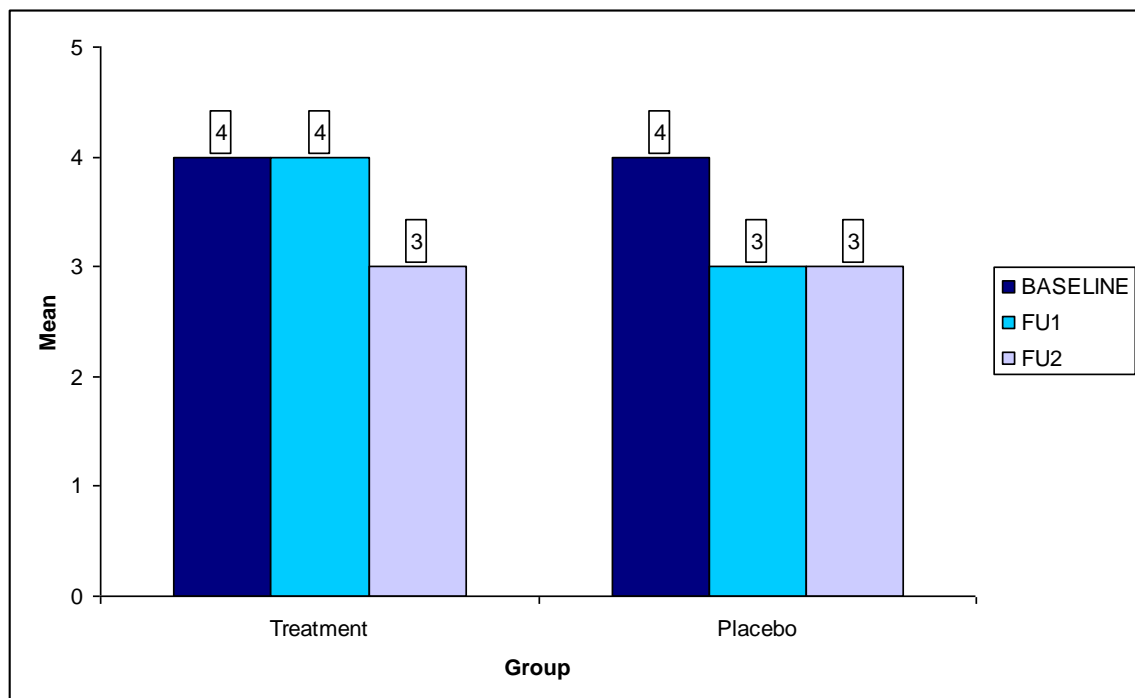


Figure 4.36 Question 21: *When I feel tired, have no energy, or just seem not to function well during the day, it is generally because I did not sleep well the night before*

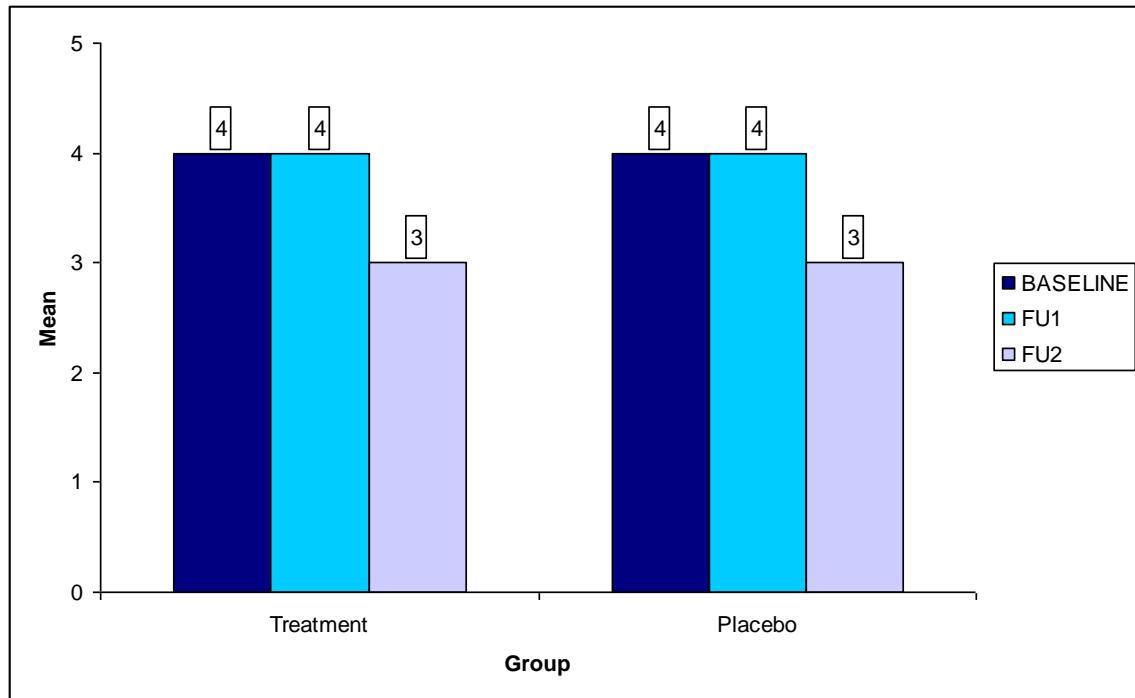


Figure 4.37 Question 22: *I get over whelmed by my thoughts at night and often feel I have no control over my racing mind*

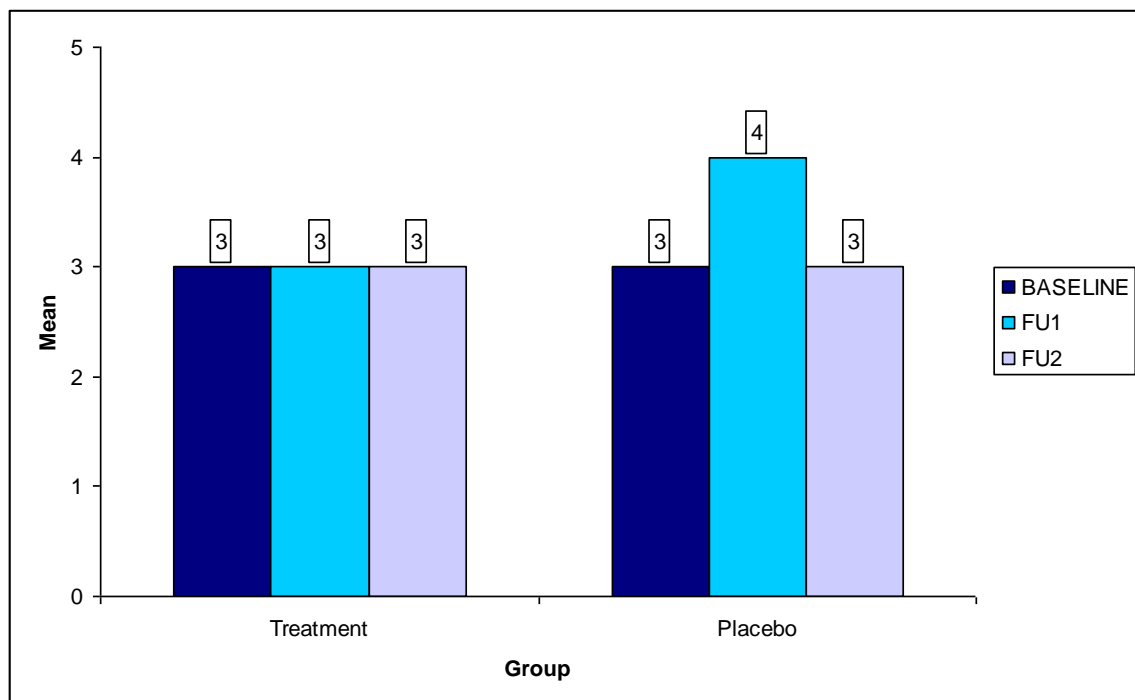


Figure 4.38 Question 23: *I feel I can still lead a satisfactory life despite sleep difficulties*

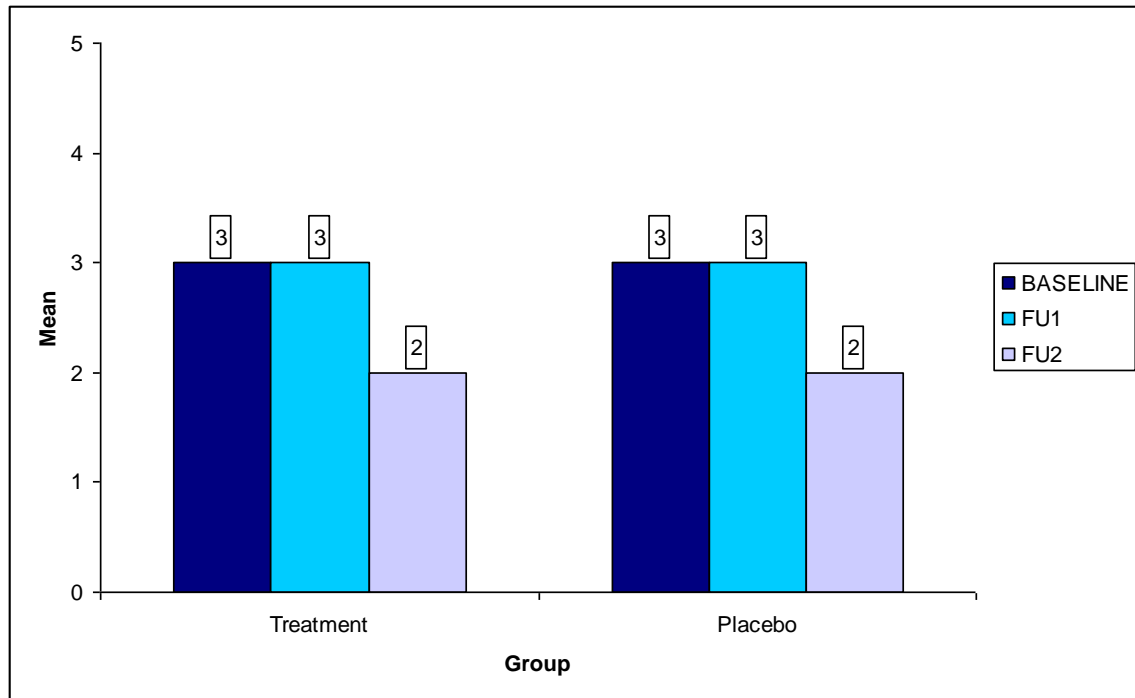


Figure 4.39 Question 24: *I believe insomnia is essentially the result of a chemical imbalance*

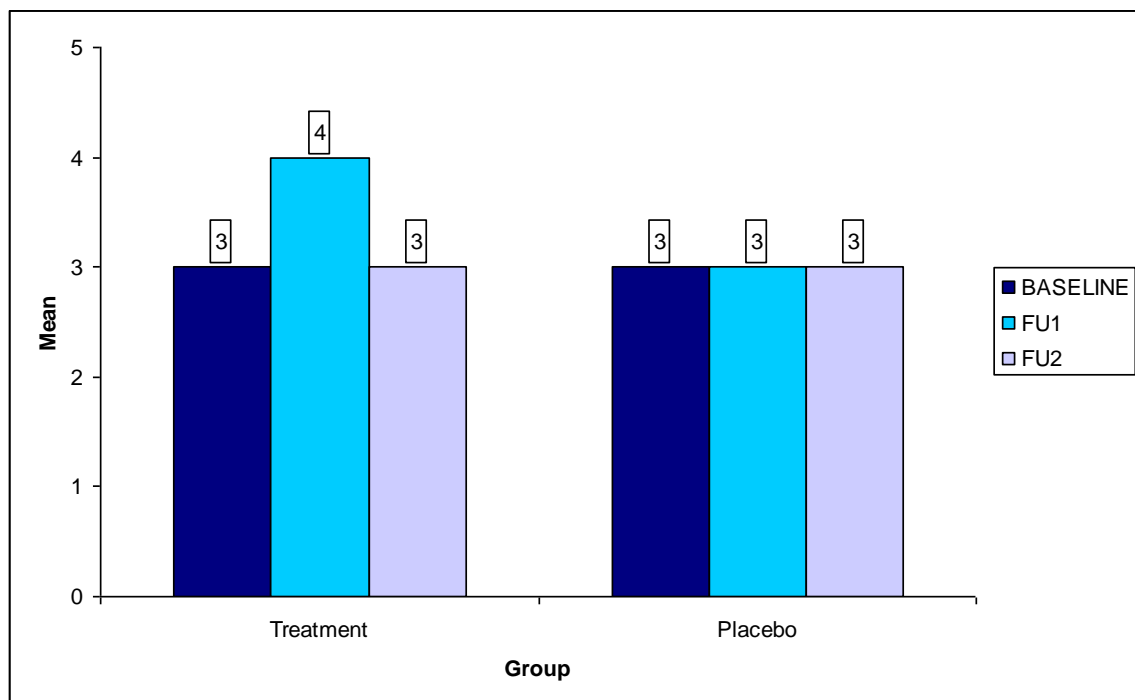


Figure 4.40 Question 25: *I feel insomnia is ruining my ability to enjoy life and prevents me from doing what I want*

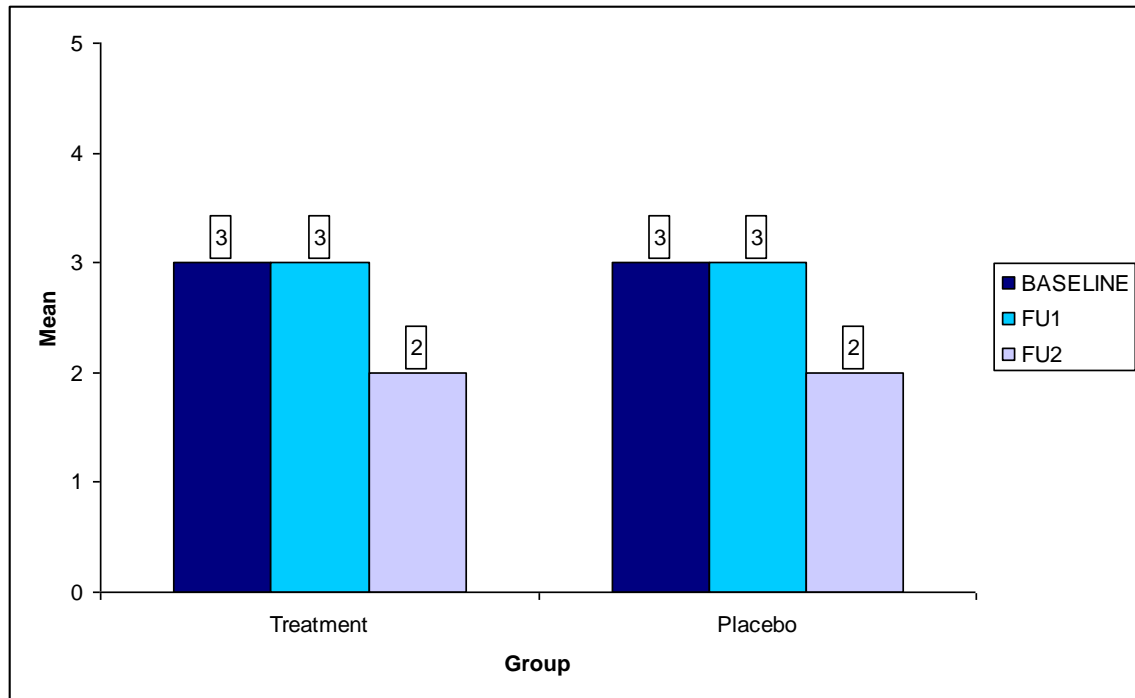


Figure 4.41 Question 26: *I avoid or cancel obligations (social, family, occupational) after a poor night's sleep*

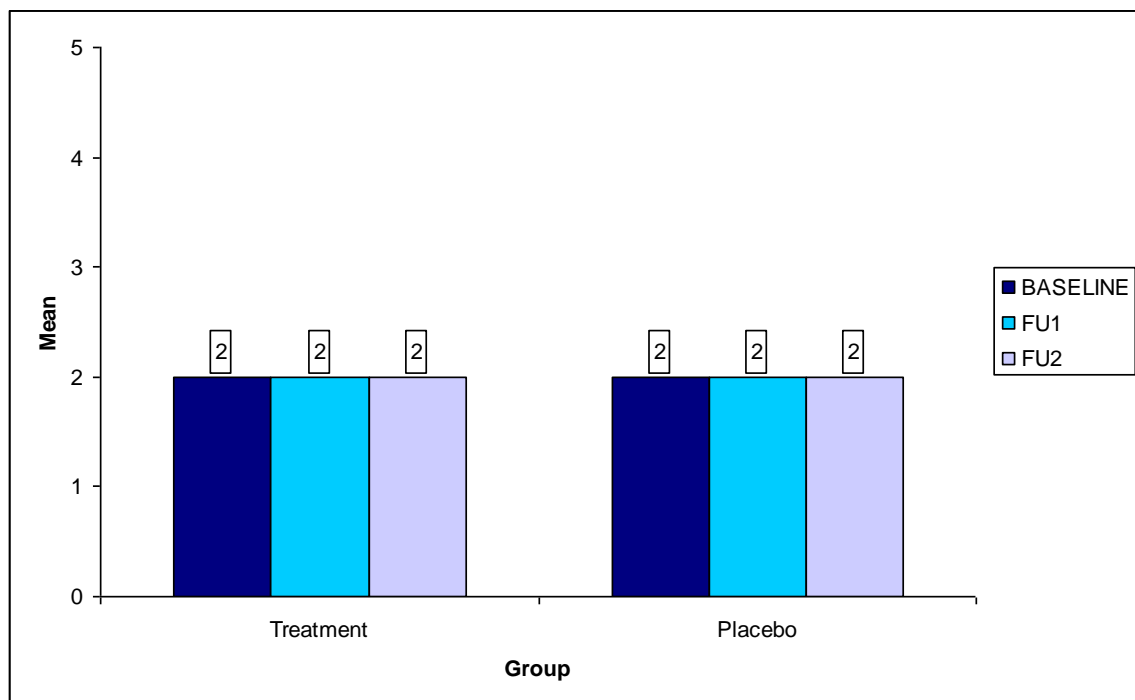


Figure 4.42 Question 27: *A "nightcap" before bedtime is a good solution to sleep problems*

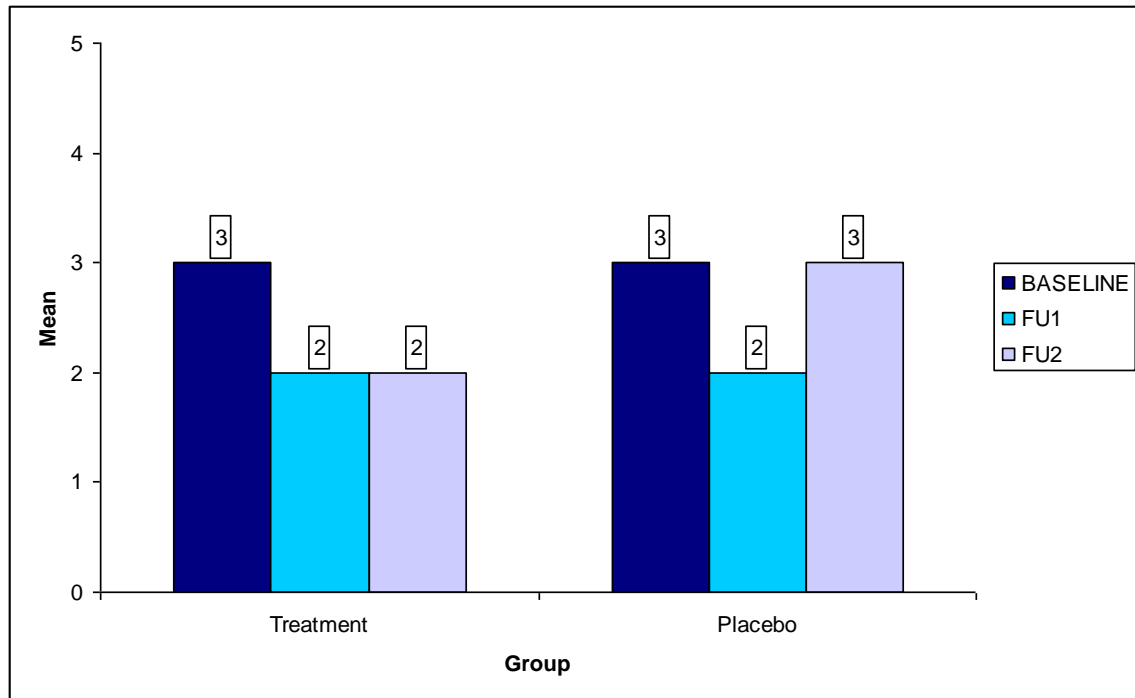


Figure 4.43 Question 28: *Medication is probably the only solution to sleeplessness*

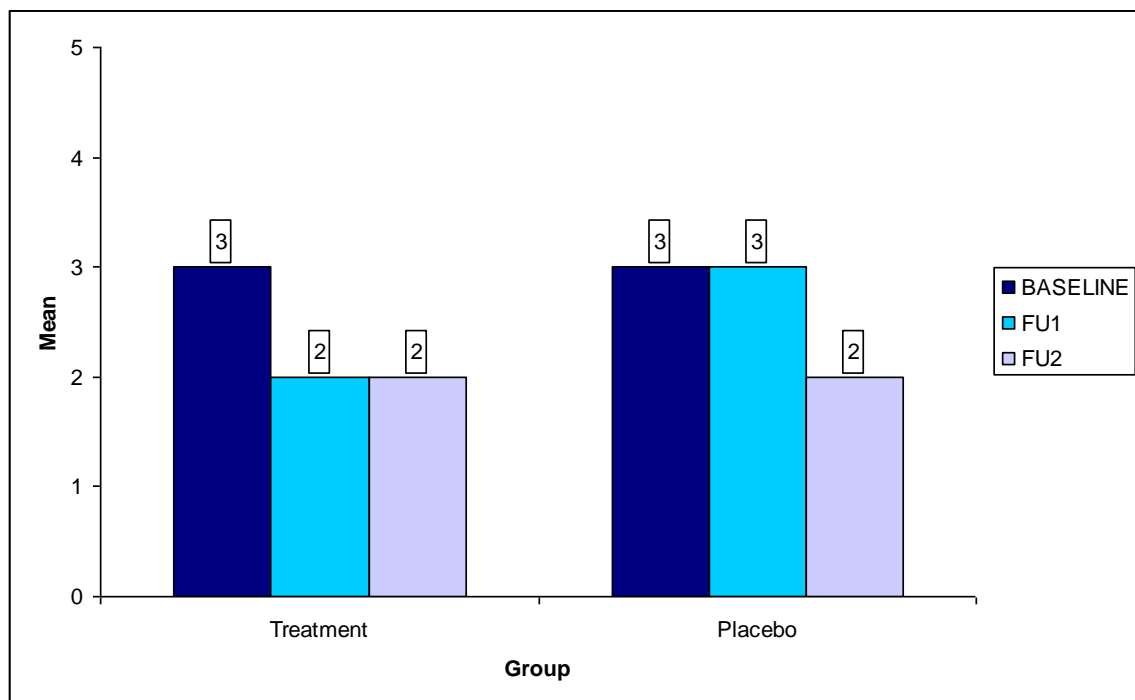


Figure 4.44 Question 29: *My sleep is getting worse all the time, and I don't believe anyone can help*

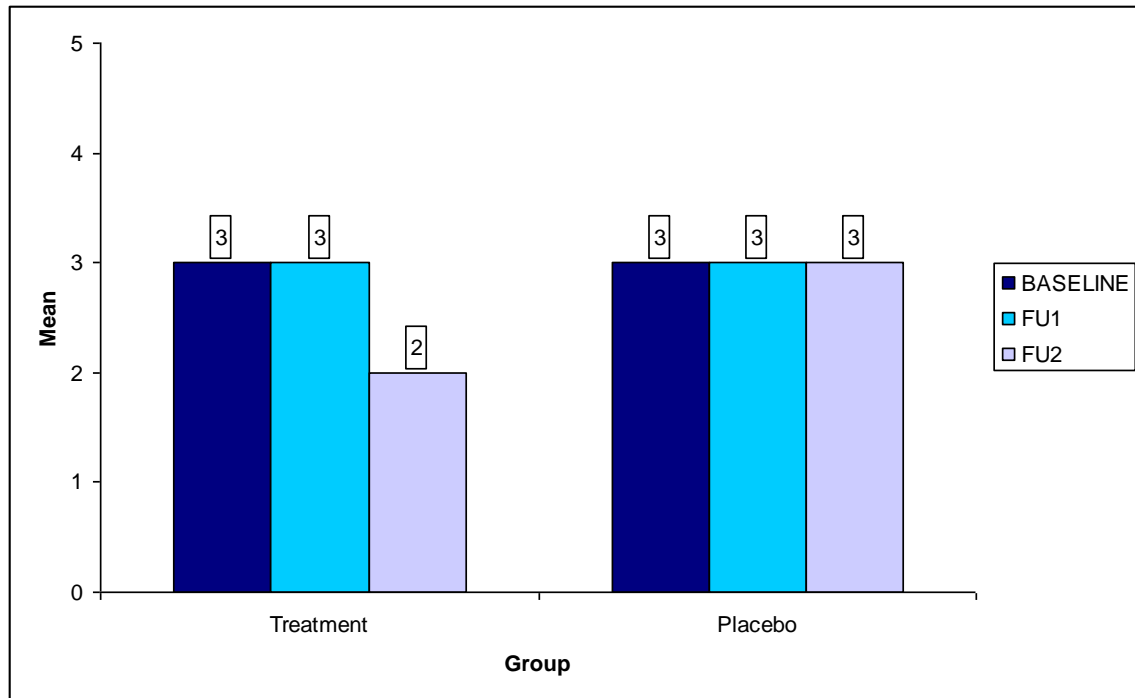


Figure 4.45 Question 30: *It usually shows in my physical appearance when I haven't slept well*

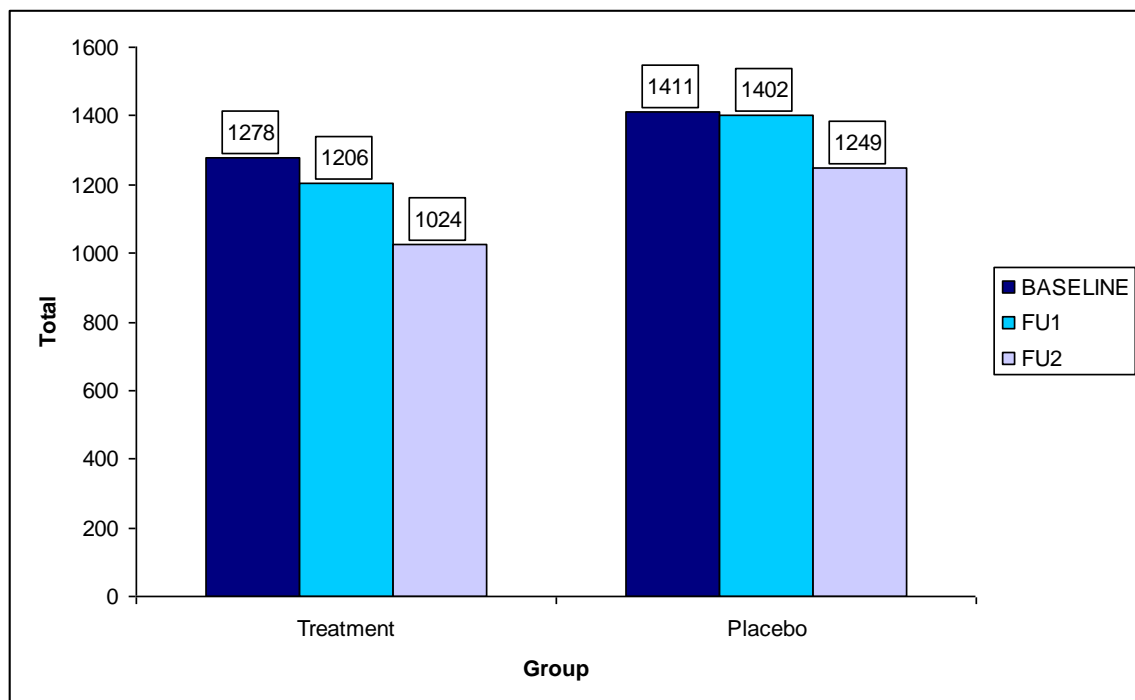


Figure 4.46 Total scores of questions - DBAS

4.4 PROCEDURE 2 (INTER-GROUP): KRUSKAL WALLIS TEST

4.4.1 SLEEP DIARY (*Appendix A*)

Table 4.8 Sleep Diary: Comparison of net gains (i.e. less baseline values) in hours slept between groups –

Week 2	Week 3	Week 4
.000*	.002*	.000*

As can be seen from Table 4.8, there are significant differences between all weeks.

Table 4.9 Sleep Diary: Comparison between groups using total hours of sleep

TOT. HRS W1 (Baseline)	TOT. HRS W2	TOT. HRS W3	TOT. HRS W4
.724	.004*	.042*	.036*

As can be seen from Table 4.9, there are significant differences in weeks 2, 3 and 4.

4.4.2 SLEEP IMPAIRMENT INDEX

Table 4.10 Inter - group analysis – SII

Question	Consult 1 (baseline)	Follow – up 1	Follow - up 2
1a	.423	.018*	.003*
1b	.042*	.005*	.000*
1c	.049*	.001*	.000*
2	.117	.012*	.000*
3	.293	.025*	.000*
4	.724	.245	.001*
5	.770	.006*	.000*
6a	.710	.000*	.000*
6b	.416	.880	.099
6c	.563	.234	.004*
6d	.632	.002*	.000*

*: Significant values

4.4.3 DYSFUNCTIONAL BELIEFS AND ATTITUDES ABOUT SLEEP SCALE

Table 4.11 Inter group analysis – DBAS

Question	Consult 1 (baseline)	Follow – up 1	Follow - up 2
1	0.438	0.828	0.359
2	0.504	0.337	0.697
3	0.964	0.893	0.241
4	0.566	0.223	0.447
5	0.095	0.842	0.622
6	0.541	0.325	0.075
7	0.733	0.697	0.694
8	0.339	0.568	0.438
90	0.747	0.732	0.965
10	0.470	0.334	0.381
11	0.610	0.847	0.678
12	0.617	0.751	0.965
13	0.180	0.396	0.932
14	0.874	0.343	0.752
15	0.157	0.837	0.672
16	0.746	0.846	0.771
17	0.491	0.815	0.473
18	0.524	0.357	0.149
19	0.456	0.630	0.148

20	0.332	0.002*	0.083
21	0.983	0.117	0.682
22	0.525	0.515	0.898
23	0.130	0.569	0.436
24	0.844	0.480	0.796
25	0.848	0.745	0.415
26	0.214	0.780	0.399
27	0.624	0.603	0.148
28	0.966	0.514	0.040*
29	0.479	0.029*	0.547
30	0.382	0.781	0.162
Total:	0.467	0.647	0.244

* Significant values

4.5 HOMOEOPATHIC REMEDIES PRESCRIBED

19 Homoeopathic remedies were prescribed during the study. Figure 4.47 illustrates the percentage of remedies prescribed for both treatment and placebo groups.

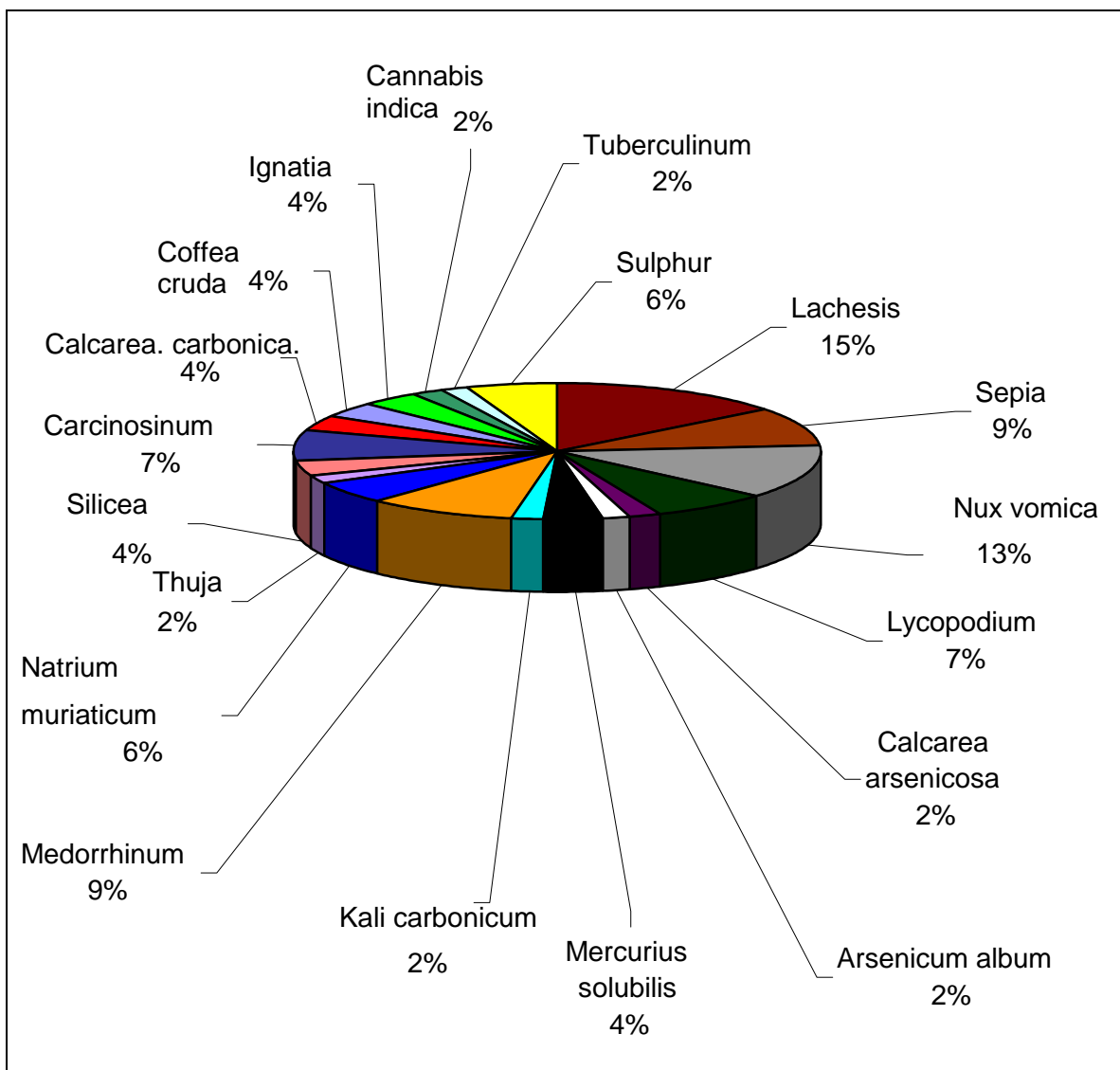


Figure 4.47 Percentage of remedies prescribed in the study (both groups)

There were 12 remedies prescribed and dispensed to the treatment group.

Figure 4.48 illustrates the percentage of the various remedies prescribed in this group.

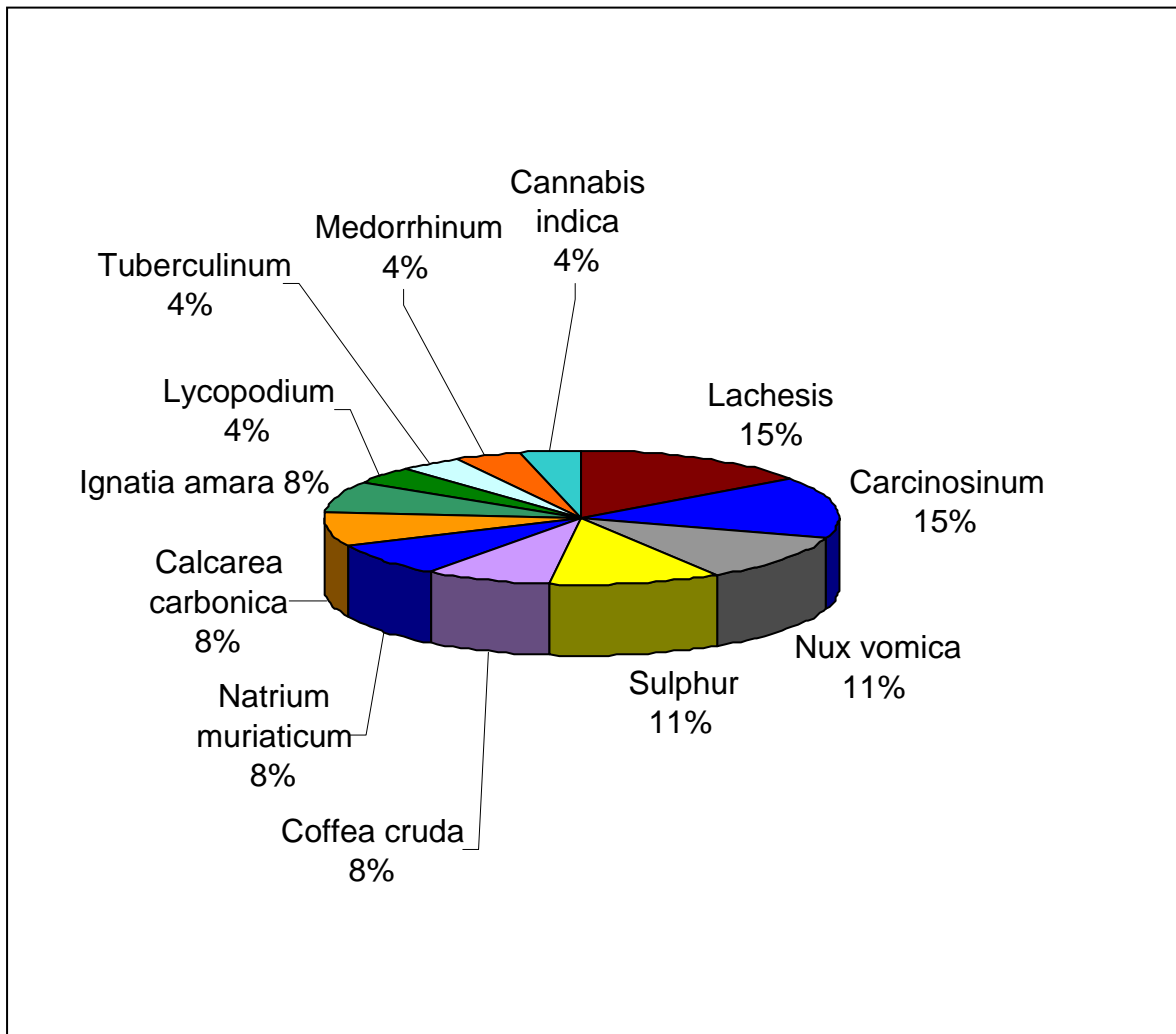


Figure 4.48 Percentage of remedies prescribed in the treatment group

There were 12 remedies prescribed but not dispensed to the participants in the placebo group until the end of the study. Figure 4.49 illustrates the percentage of the various remedies prescribed in the placebo group.

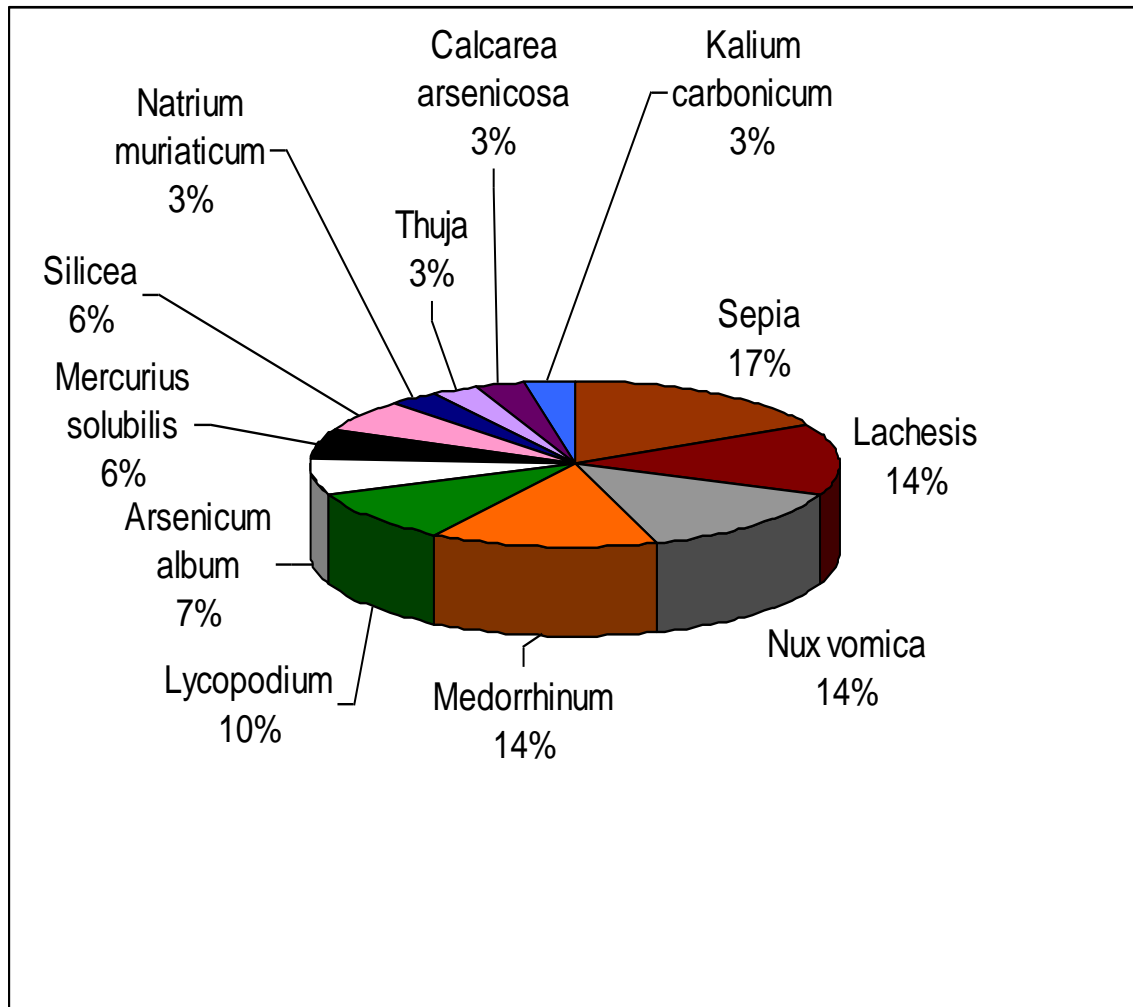


Figure 4.49 Percentage of remedies prescribed in the placebo group

4.6 HOMOEOPATHIC POTENCIES PRESCRIBED

The various remedies were prescribed at different potencies - 30CH, 200CH, 1M OR 10M. Table 4.12 is a representation of the remedies and their corresponding potencies prescribed in the study, taking both groups into account.

Table 4.12 Number of potencies prescribed per group

REMEDY	POTENCY	<i>TREATMENT GROUP NO. PRESCRIBED</i>	<i>PLACEBO GROUP NO. PRESCRIBED</i>
Lachesis	30CH 200CH 1M	1 4 5	1 10 1
Nux Vomica	30CH 200CH 1M 10M	1 4 4 -	2 5 2 1
Sepia	30CH 200CH 1M 10M	- - - -	2 8 2 1
Medorrhinum	30CH 200CH 1M 10M	- 2 - -	2 3 4 1
Carcinosinum	30CH 200CH 1M 10M	- 7 2 1	- - - -
Lycopodium	30CH 200CH 1M	1 1 1	1 4 2
Natrium muriaticum	30CH 200CH 1M	- 4 -	1 1 1
Sulphur	30CH 200CH 1M	4 1 4	- - -
Coffea cruda	30CH 200CH 1M	- 6 -	- - -

Calcarea carbonica	30CH	-	-
	200CH	4	-
	1M	1	-
	10M	1	-
Ignatia amara	30CH	1	-
	200CH	2	-
	1M	3	-
Silicea	30CH	-	-
	200CH	-	3
	1M	-	1
Mercurius solubilis	30CH	-	-
	200CH	-	3
	1M	-	2
Tuberculinum	30CH	1	-
	200CH	1	-
	1M	1	-
Arsenicum album	30CH	-	1
	200CH	-	1
	1M	-	2
Thuja	30CH	-	-
	200CH	-	3
	1M	-	-
Cannabis indica	30CH	-	-
	200CH	2	-
	1M	1	-
Kalium carbonicum	30CH	-	1
	200CH	-	1
	1M	-	1
Calcarea arsenicosa	30CH	-	3
	200CH	-	-
	1M	-	-

Figure 4.50 illustrates the percentage of potencies prescribed during the study. This takes both treatment and placebo groups into consideration.

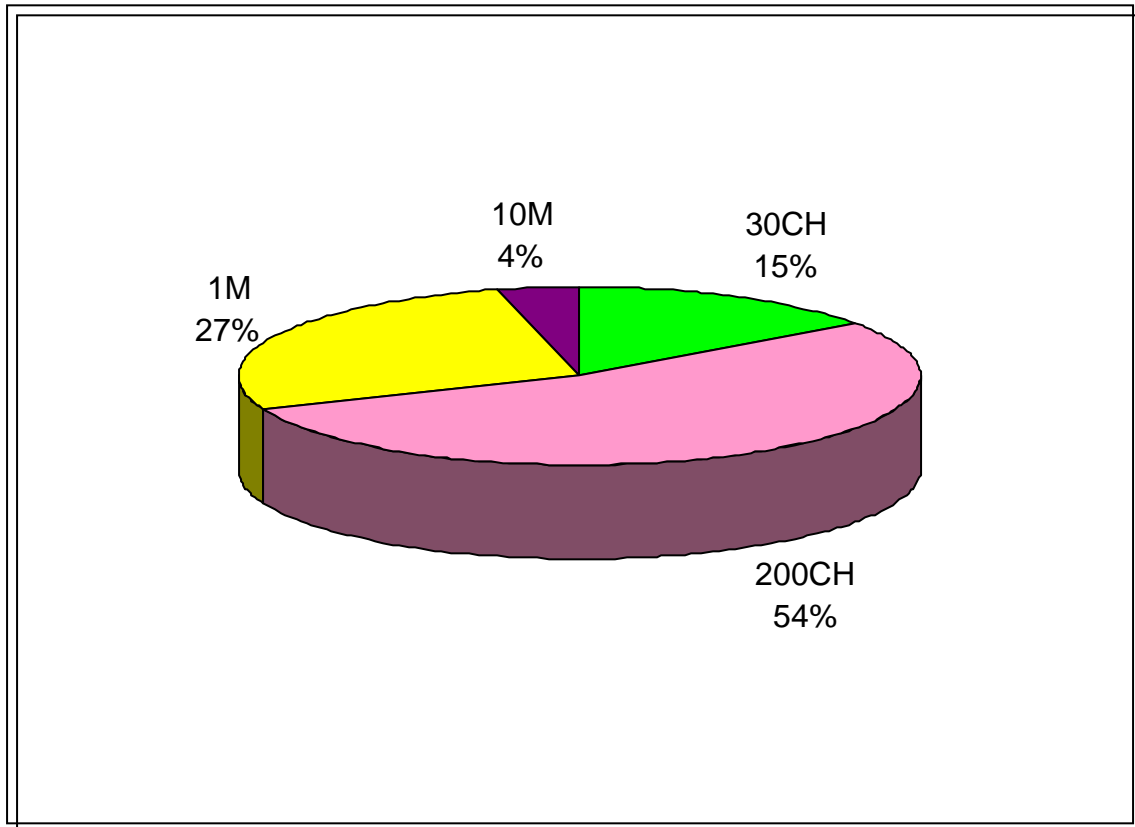


Figure 4.50 Percentage of potencies prescribed in the study (both groups)

Figure 4.51 and Figure 4.52 illustrates the number and percentage of potencies prescribed in the treatment group only.

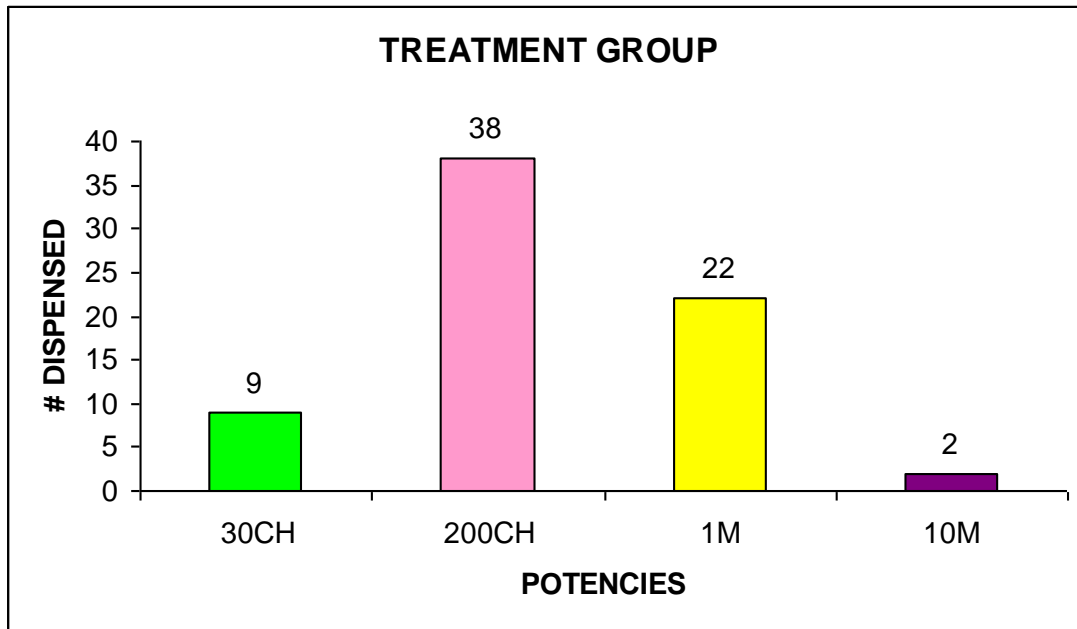


Figure 4.51 Number of potencies prescribed in the treatment group

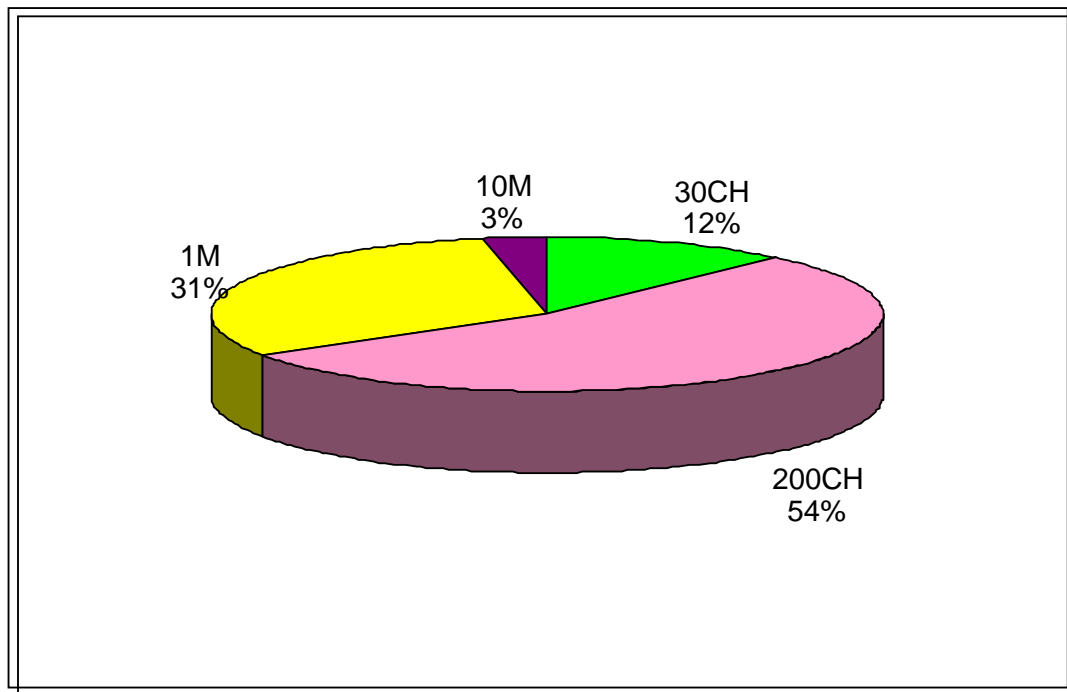


Figure 4.52 Percentage of potencies prescribed in the treatment group

Figure 4.53 and Figure 4.54 illustrates the number and percentage of potencies prescribed in the placebo group only.

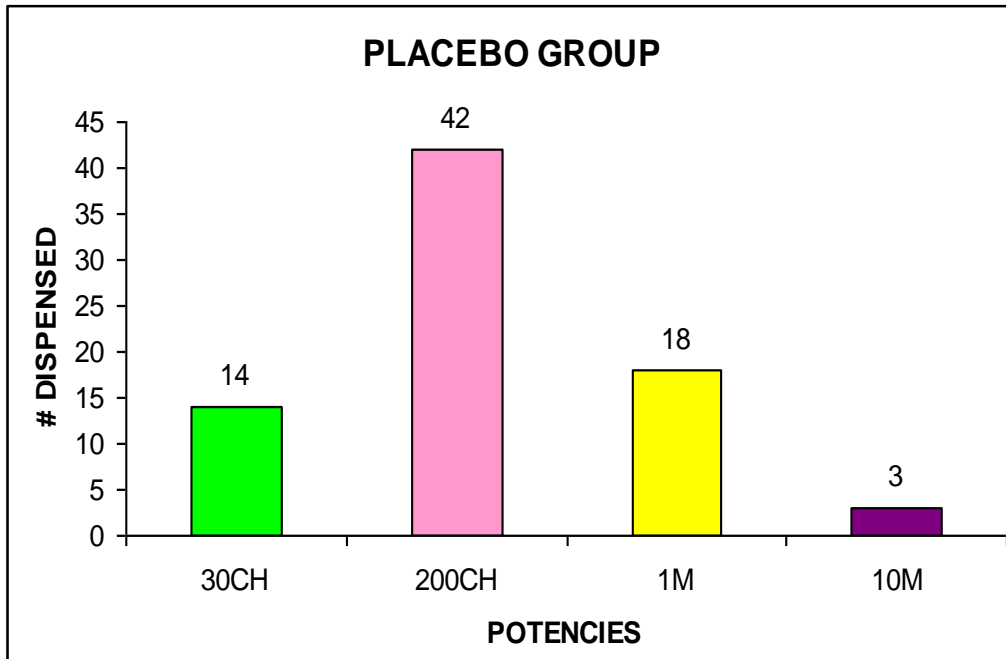


Figure 4.53 Number of potencies prescribed in the placebo group

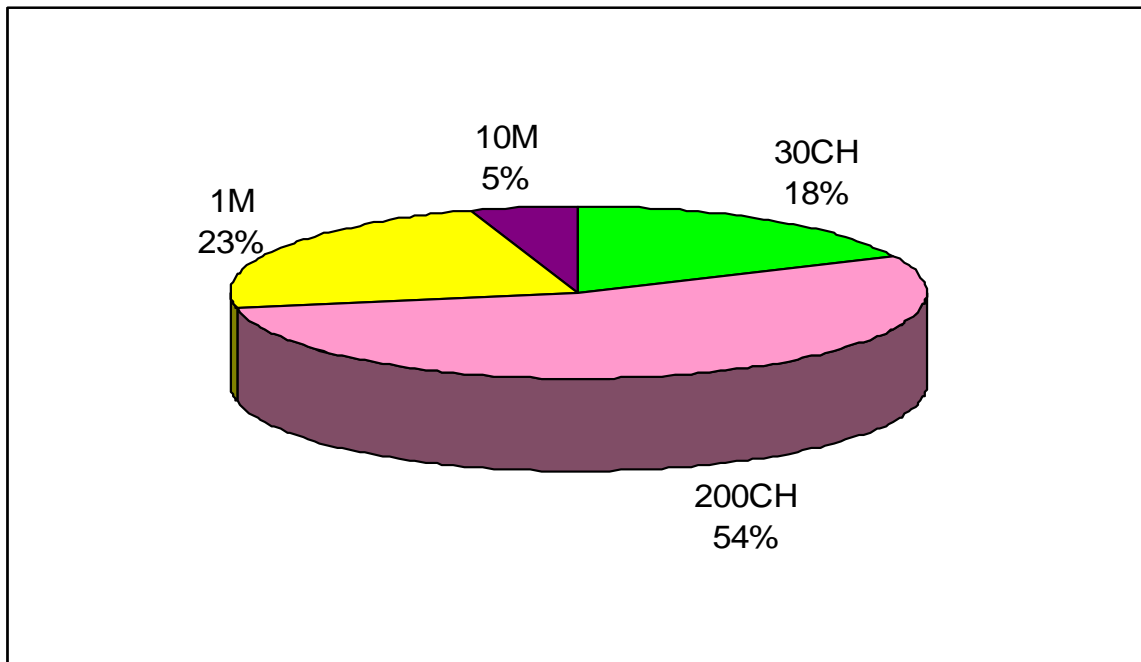


Figure 4.54 Percentage of potencies prescribed in the placebo group

CHAPTER 5

DISCUSSION

This double-blind placebo-controlled study was conducted to determine the efficacy of the homoeopathic simillimum approach in the treatment of chronic primary insomnia, in terms of patient's perception of response to treatment.

As can be seen from Table 4.1, intra-group analysis (within each group) of Sleep Diary readings indicated a significant difference in the total hours of sleep in the Treatment Group between baseline and weeks 2, 3 and 4, as well as between weeks 2 and 4. The total hours of sleep in the Treatment Group at baseline (week 1) was 35 hours. There was a significant increase in total hours of sleep to 45 hours at week 2. The total hours of sleep in week 3 was 43 hours and at week 4 it stood at 41 hours of sleep at the end of the study

The total hours of sleep improved significantly within the first week of treatment. The total hours slept then remained fairly consistent in the following weeks. This is the reason for the lack of significant differences between week 2 and week 3, as well as week 3 and week 4.

However, the total hours of sleep at the end of the study (41 hours) was still significantly higher than baseline (35 hours) ($p = 0.002$).

As can be seen from Table 4.1, there were no significant differences between any of the weeks in the Placebo Group. Upon calculating means, it was revealed that there was an average net loss of 2 hours of sleep within the first week of treatment, in the Placebo Group. The readings then returned to baseline levels at week 3. At the last consultation, there was a net gain of 1 hour of sleep.

Inter-group analysis (between the groups) of Sleep Diary readings (see Table 4.9) indicates that the degree of sleeplessness was comparable between the two groups at baseline. When comparing the net gains in hours slept and total hours of sleep per week between groups (see Table 4.8 and 4.9), it is noted that there were significant differences between the groups at all weeks with the greatest difference being in week 2. The total hours gained in the Treatment Group is significant compared to that of the Placebo Group ($p = 0.36$).

Intra-group analysis of Sleep Impairment Index (SII) readings comparing baseline and Follow-Up 1, within the Treatment Group, indicated significant differences in 9 of the 11 questions. At Follow-Up 1 Questions 1c and 6c did not have significant differences (see Table 4.2). Question 1c was a rating of problems with waking up too early and Question 6c was a reflection of bad sleeping habits. However, when comparing Follow-Up 1 and Follow-Up 2 as well as Follow-Up 2 and baseline (see Tables 4.3 and 4.4), significant differences were noted in all questions. Perceptions may have changed through the weeks and confidence in the researcher, as well as the homoeopathic medicines, was increased.

According to intra-group analysis, significant differences were noted in 2 of the 11 questions in the Placebo Group, when comparing SII readings between Follow-Up 1 and Follow-Up 2 (see Table 4.3), one week after the prescription of “medication”. These occurred in Questions 1a and 6a only. Question 1a rated the participants’ difficulty in falling asleep, and Question 6a rated the severity of cognitive disturbances on sleep. However, there were no significant differences in any question when comparing baseline to Follow-Up 1 and Follow-Up 2 (see Tables 4.2 and 4.4).

Inter-group analysis of SII readings (see Table 4.10) resulted in significant differences in 2 of the 11 questions at baseline. This occurred in Questions 1b and 1c. However, these were only marginally different (0.42 and 0.49 respectively). At Follow-Up 1 (FU1), there were significant differences in 8 of the 11 questions. By the end of the trial (at Follow-Up 2) the significant differences had increased to 10 of the 11 questions.

Intra-group analysis of Dysfunctional Beliefs and Attitudes about Sleep Scale readings comparing baseline and Follow-Up 1, within the Treatment Group, indicated significant differences in 10 of the 31 questions (see Table 4.5). When comparing Follow-Up 1 and Follow-Up 2 as well as baseline and Follow-Up 2, there were significant differences in 14 and 15 of the 31 questions respectively. This indicates a delayed positive change after Follow-Up 1 (see Tables 4.6 and 4.7).

When comparing baseline and Follow-Up 1 within the Placebo Group, there were significant differences in 2 of the 31 questions (see Table 4.5). However, this increased to 9 of 31 questions when comparing Follow-Up 1 and Follow-Up 2 (see Table 4.6) and 5 of 31 questions at the end of the study (see Table 4.7).

As can be seen from Table 4.11, inter-group analysis of DBAS scores revealed no significant differences at baseline. This indicates that all participants entered the study with no significant dissimilar dysfunctional beliefs and attitudes.

Therefore the two groups were comparable. At Follow-Up 1, significant differences were noted for Questions 20 ($p = 0.002$) and 29 ($p = 0.029$) only.

Question 20 assessed the participants' ability to manage the negative consequences of disturbed sleep. Question 29 stated, "My sleep is getting worse all the time, and I don't believe anyone can help me."

There was a significant difference for Question 28 ($p = 0.040$) as measured at Follow-Up 2. Question 28 stated, "Medication is probably the only solution to sleeplessness." This result reveals the participants' belief in medications prescribed. This negative belief demonstrates the despondency of participants. Treating chronic insomnia should therefore involve a multi-disciplinary approach. Cognitive-behavioural therapies should be sought as a component of treatment.

The DBAS has proved extremely useful as a therapeutic tool for non-pharmacologic interventions such as cognitive therapy sessions. However, this measurement tool may not have been appropriate for the purposes of this trial as some questions (e.g. Q7: When I have trouble getting to sleep, I should stay in bed and try harder) were not directly suited for a pharmacologic intervention, like Homoeopathy. In this study, no attempt was made to change cognitive perceptions through psychological analysis and verbal exchange, as there is in a cognitive therapy session. It is suggested that a modified DBAS or another measurement tool be selected for future studies. The subjectivity of the questionnaires must also be considered. A more objective method may have showed more accurate findings.

The placebo effect also needs to be addressed. The placebo effect is considered as an example of mind-body relation that depends on subconscious interactions between the doctor, the treatment process, and the patient. A physician's attributes, dress, demeanour, voice and body language each contribute to a marked placebo effect. The benefit of placebo is considered transient, although its effects are not always short-lived (Pearce, 1995). Due to the clear significant differences between the Treatment Group and the Placebo Group in terms of the Sleep Diary and the SII, one can conclude that the placebo effect was not a major factor in this study.

A review of the related literature revealed three studies similar to this one. Pellow (2002) and Roohani (1997) assessed the efficacy of simillimum treatment and complex remedy prescription for secondary insomnia respectively.

Lankesar (2004) assessed the efficacy of simillimum treatment for post-traumatic stress disorder. All three studies concluded that homoeopathic treatment was effective, although only Roohani used statistical analysis.

The most similar study to this was a qualitative analysis conducted by Pellow (2002). The study was not a double-blind-placebo-controlled study and the sample size consisted of 10 females only. A descriptive study of individual cases was compiled based on the readings of the measurement tools. Statistical analyses were not conducted.

Thus, this study concurred with the findings of the above three studies; that homoeopathy can be effective in treating insomnia.

However, a direct comparison of results is not possible due to the many methodological differences of the studies (as discussed in Chapter 2) and the qualitative analysis of their findings. This study used quantitative analysis to form a statistically viable research project.

As can be seen in Figure 4.47, Lachesis and Nux vomica were the most common remedies prescribed in the study. Lachesis was prescribed in 15% of the cases and Nux vomica in 13% of the cases, taking both treatment and placebo groups into account.

Lachesis and Carcinosinum were the most commonly prescribed remedies in the treatment group (figure 4.48). Both were prescribed in 15% of the cases. It is interesting to note that Carcinosinum was not prescribed to any participants of the placebo group. Carcinosinum was the fifth highest remedy prescribed in the study and occurred in 7% of the total cases taken in the study.

Sepia was the most common remedy prescribed in the placebo group, being prescribed in 17% of the cases in the placebo group (figure 4.28). Lachesis, Nux Vomica and Medorrhinum were prescribed in 14% of the cases. Sepia was not prescribed to any of the participants in the treatment group.

Due to the high occurrence of Lachesis, Carcinosinum and Nux vomica in the study, it is interesting to note the mental disposition and sleeping difficulties reflected in the materia medica of these remedies.

The person needing Lachesis has qualities of competitiveness, aggressiveness, attractiveness, sexuality, clairvoyance and deception. They are extremely talkative and jealous individuals whose mental labour is best performed at

night (Sankaran, 1997: 113). Many individuals are suspicious and have a quality of religious mania. They often experience sleepiness, yet are unable to fall asleep. Their sleep is disturbed by the least noise and they are sometimes afraid to go to sleep for fear that they will die before they awake (Boericke, 1999: 387). The sleeplessness is a result of the anxiety experienced, especially before midnight. They often awake at night and can not sleep thereafter. Their dreams are frightful and are usually of snakes and death. Even short naps are disturbed by frightful dreams and the person springs up in bed with terror and a feeling of suffocation with palpitations (Vermeulen, 2000: 929).

The main feeling of people needing Carcinosinum is that one's survival depends on performing tasks which one feels incapable of doing. They often go beyond their capacity, to the utmost in the hope of success, because failure means death and destruction. These individuals have a history of too much responsibility at a young age, having very high expectations placed on them and excessive parental control during childhood. They reach out for perfection in all they do. This need for perfection makes them fastidious in all spheres of their life to the point of being faultless (Sankaran, 1997: 55). This remedy is noted for the sleeping difficulties that patients experience. There is tremendous sleeplessness in children from birth. Therefore it is commonly prescribed for chronic sleeplessness (Vermeulan, 2000: 412).

The main expressions of people needing Nux vomica, is that they are hard, zealous, ambitious and impatient. They are hard task masters and are irritable, passionate and fastidious (Vermeulan, 2000: 1151 – 1152). These individuals are usually disposed to reproach others and may have a sullen disposition. They do a good deal of mental work and lead a sedentary lifestyle. This indoor life with business cares and anxieties leads to the excessive use of coffee, wine, tobacco and other stimulants. These conditions produce irritable and hypersensitive responses e.g. the person cannot bear noises, odours or light, which Nux vomica will soothe and calm. There is extreme difficulty in initiating sleep due to the occurrence of rapid thoughts about business and finances. They usually wake in the morning feeling wretched. These people are usually drowsy after meals and in early evening. Their dreams are full of bustle and hurry. They are better after a short sleep, unless aroused (Boericke: 1999: 477 – 478).

Considering the characteristics of Lachesis, Carcininum and Nux vomica it is understandable that they featured prominently in the study.

On careful analyses of the prescriptions to participants in the treatment group, it is observed that 11 of the 14 participants received the same remedy at both consultations. Any need for repetition is determined by the response to the first dose. A favourable response followed by a return of some or all symptoms indicates a repetition of the remedy (Carlston, 2003:116).

After selecting the appropriate remedy, a homoeopath makes a decision about the potency of the remedy. Common potencies prescribed in this study include a medium potency of 30CH, a high potency of 200CH, and higher levels of potency consisting of 1M and 10M. As can be seen in figure 4.29, 200CH was the most common potency prescribed. It was prescribed in 54% of the total cases in the study (both treatment and placebo groups were considered). 1M was prescribed in 27% of cases. Figure 4.31 illustrates similar results, with 54% of the participants in the treatment group receiving their remedies in 200CH and 31% in the 1M potency level.

According to Carlston (2003: 116), the homoeopath must first decide whether the key indicating symptoms (mental, physical or emotional) are mild or intense. If the prescribing symptoms are intense, particularly the mental or emotional symptoms, a high potency is required. The homoeopath may choose the 200CH, 1M or 10M potency level. Carlston further explains that patients who are chronically ill, with a few clear symptoms that are intense, or start from a single point in time, may be easily treated with doses of a high-potency centesimal remedy such as 200CH or higher. de Schepper (2001: 75) also recommends the use of 200CH for strong conditions such as emotional or physical traumas. Insomnia is considered a pathology related to the mental plane.

It is often accompanied by intense emotions and therefore relates to the emotional plane of an individual as well. It is therefore understandable that the 200CH potency level was the most common potency used in the study.

7 of the 14 participants in the treatment group received a higher potency of the same remedy at their first follow-up. 4 of the 14 participants received their remedies in ascending potencies (30CH, 200CH and 1M), 3 of which received it at the initial consultation. An ascending collective single dose prescription is a variant of the principle of single remedy prescription (see Chapter 2, 2.10.2.3) This method is employed to ensure that the remedy has 'taken hold' and to minimise any adverse reactions to the remedy in hypersensitive people. This form of prescription makes use of three doses of the same remedy in ascending potencies, e.g. 30CH – 200CH – 1M, at intervals of 4 – 24 hours (Watson, 1995: 16). In this study, instructions were that all remedies be taken every 24 hours.

Although the study revealed positive results, certain methodological recommendations need to be considered. The first Follow-Up consult was 1 week after the initial prescription. Patients may have benefited from a longer Follow-Up period. The sample size of this study was 30 participants. A larger number sample size would ensure parametric statistical analysis.

CHAPTER 6

CONCLUSION AND RECOMMENDATIONS

6.1 CONCLUSION

The results of this study lead to the conclusion that homoeopathic simillimum was shown to be statistically more effective than placebo in the treatment of chronic primary insomnia in terms of Sleep Diary and SII readings.

The study showed that homoeopathy can offer significant relief for insomniacs, when the simillimum is prescribed. Therefore, homoeopathy forms a viable alternative in the treatment of chronic primary insomnia.

6.2 RECOMMENDATIONS

The following recommendations are made for further research:

1. Increase the sample size of the study.
2. Monitor patients over a longer period of time.
3. Use objective measurement tools (such as polysomnograph recordings).
4. Compare other approaches of homoeopathy in the treatment of chronic primary insomnia e.g. miasmatic prescription, complex formulas and clinical remedies.
5. Compare the use of single potencies (e.g. 200CH) only, in the treatment of chronic primary insomnia.

6. Assess the use of ascending collective single dose prescription (e.g. 30CH – 200CH -1M) only in the treatment of chronic primary insomnia.
7. Strategies to address the need to educate both the general public and health professionals about the use of homoeopathy in sleep must be generated.
8. Assessment of the benefits of cognitive behavioural strategies in combination with homoeopathy for treating chronic insomnia should be sought.
9. Compare the benefits of homoeopathic treatment to cognitive behavioural therapy, allopathic treatment, acupuncture and/or psychotherapy in the treatment of chronic primary insomnia.
10. Assess the efficacy of the common individual remedies prescribed in this study (Lachesis, Carcinosinum and/or Nux Vomica) against placebo in the treatment of chronic primary insomnia.

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APPENDIX A

SLEEP DIARY

1) Sleep sheet

S	M	T	W	T	F	S
M	T	W	T	F	S	S

Date: _____

	Midnight													Noon											
Time	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6
Awake																									
Asleep																									

2) Sleep sheet

S	M	T	W	T	F	S
M	T	W	T	F	S	S

Date: _____

	Midnight													Noon											
Time	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6
Awake																									
Asleep																									

3) Sleep sheet

S	M	T	W	T	F	S
M	T	W	T	F	S	S

Date: _____

	Midnight													Noon											
Time	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6
Awake																									
Asleep																									

4) Sleep sheet

S	M	T	W	T	F	S
M	T	W	T	F	S	S

Date: _____

	Midnight													Noon											
Time	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6
Awake																									
Asleep																									

5) Sleep sheet

Date: _____

S	M	T	W	T	F	S
M	T	W	T	F	S	S

	Midnight												Noon												
Time	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6
Awake																									
Asleep																									

6) Sleep sheet

Date: _____

S	M	T	W	T	F	S
M	T	W	T	F	S	S

	Midnight												Noon												
Time	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6
Awake																									
Asleep																									

7) Sleep sheet

Date: _____

S	M	T	W	T	F	S
M	T	W	T	F	S	S

	Midnight												Noon												
Time	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6
Awake																									
Asleep																									

APPENDIX B

DURBAN INSTITUTE OF TECHNOLOGY DEPARTMENT OF HOMOEOPATHY: RESEARCH QUESTIONS TO PATIENTS WITH CHRONIC PRIMARY INSOMNIA

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

Instructions:

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

SLEEP IMPAIRMENT INDEX (Morin, 1993:199)

1. Please rate the current severity of your insomnia problem(s) by **circling** the appropriate number:

	<u>None</u>	<u>Mild</u>	<u>Moderate</u>	<u>Severe</u>	<u>Very</u>
A Difficulty falling asleep:	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>
B Difficulty staying asleep:	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>
C Problems waking up too early:	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>

2. How dissatisfied are you with your current sleep pattern?

<u>None</u>	<u>Mild</u>	<u>Moderate</u>	<u>Severe</u>	<u>Very much</u>
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>

3. To what extent do you consider your sleep problem to interfere with your daily functioning (e.g. daytime fatigue, ability to function at work/daily chores, concentration, memory, mood, etc.)?

<u>None</u>	<u>Mild</u>	<u>Moderate</u>	<u>Severe</u>	<u>Very much</u>
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>

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

None	Mild	Moderate	Severe	Very much
1	2	3	4	5

5. How **concerned** are you about your current sleep problem?

None	Mild	Moderate	Severe	Very much
1	2	3	4	5

6. To what extent do you believe the following factors are contributing to your sleep problem?

	None	Mild	Mod.	Sev.	Much
A Cognitive disturbances (racing thoughts at night):	1	2	3	4	5
B Somatic disturbances (muscular tension, pain):	1	2	3	4	5
C Bad sleeping habits:	1	2	3	4	5
D Natural aging process:	1	2	3	4	5

APPENDIX C

RESEARCH QUESTIONS TO PATIENTS WITH CHRONIC PRIMARY INSOMNIA

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

Instructions:

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

DYSFUNCTIONAL BELIEFS AND ATTITUDES ABOUT SLEEP SCALE (Morin 1993: 201–204)

*Please indicate to what extent you personally agree or disagree with each statement. For each statement, **circle** the appropriate number.*

1. I need 8 hours of sleep to feel refreshed and function well during the day.

Strongly disagree _____ Strongly agree
1 2 3 4 5

2. When I don't get a proper amount of sleep on a given night, I need to catch up on the next day by napping or on the next night by sleeping longer.

Strongly disagree _____ Strongly agree
1 2 3 4 5

3. Because I am getting older, I need less sleep.

Strongly disagree _____ Strongly agree
1 2 3 4 5

4. I am worried that if I go for one or two nights without sleep, I may have a nervous breakdown.

Strongly disagree _____ Strongly agree
1 2 3 4 5

5. I am concerned that chronic insomnia may have serious consequences for my physical health.

Strongly disagree _____ Strongly agree
1 2 3 4 5

6. By spending more time in bed, I usually get more sleep and feel better the next day.

Strongly disagree _____ Strongly agree
1 2 3 4 5

7. When I have trouble getting to sleep, I should stay in bed and try harder.

Strongly disagree _____ Strongly agree
1 2 3 4 5

8. I am worried that I may lose control over my abilities to sleep.

Strongly disagree _____ Strongly agree
1 2 3 4 5

9. Because I am getting older, I should go to bed earlier in the evening.

Strongly disagree _____ Strongly agree
1 2 3 4 5

10. After a poor night's sleep, I know that it will interfere with my daily activities on the next day.

Strongly disagree _____ Strongly agree
1 2 3 4 5

11. In order to be alert and function well during the day, I am better off taking a sleeping pill rather than having a poor night's sleep.

Strongly disagree _____ Strongly agree
1 2 3 4 5

12. When I feel irritable, depressed, or anxious during the day, it is mostly because I did not sleep well the night before.

Strongly disagree _____ Strongly agree
1 2 3 4 5

13. Because my bed partner falls asleep as soon as his or her head hits the pillow and stays asleep through the night, I should be able to do so too.

Strongly disagree _____ Strongly agree
1 2 3 4 5

14. I feel that insomnia is basically the result of aging, and there isn't much that can be done about this problem.

Strongly disagree _____ Strongly agree
1 2 3 4 5

15. I am sometimes afraid of dying in my sleep.

Strongly disagree _____ Strongly agree
1 2 3 4 5

16. When I have a good night's sleep, I know that I will have to pay for it on the following night.

Strongly disagree _____ Strongly agree
1 2 3 4 5

17. When I sleep poorly on one night, I know it will disturb my sleep schedule for the whole week.

Strongly disagree _____ Strongly agree
1 2 3 4 5

18. Without an adequate night's sleep, I can hardly function the next day.

Strongly disagree _____ Strongly agree
1 2 3 4 5

19. I can't ever predict whether I'll have a good or poor night's sleep.

Strongly disagree _____ Strongly agree
1 2 3 4 5

20. I have little ability to manage the negative consequences of disturbed sleep.

Strongly disagree _____ Strongly agree
1 2 3 4 5

21. When I feel tired, have no energy, or just seem not to function well during the day, it is generally because I did not sleep well the night before.

Strongly disagree _____ Strongly agree
1 2 3 4 5

22. I get over whelmed by my thoughts at night and often feel I have no control over my racing mind.

Strongly disagree _____ Strongly agree
1 2 3 4 5

23. I feel I can still lead a satisfactory life despite sleep difficulties.

Strongly agree _____ Strongly disagree
1 2 3 4 5

24. I believe insomnia is essentially the result of a chemical imbalance.

Strongly disagree _____ Strongly agree
1 2 3 4 5

25. I feel insomnia is ruining my ability to enjoy life and prevents me from doing what I want.

Strongly disagree _____ Strongly agree
1 2 3 4 5

26. I avoid or cancel obligations (social, family, occupational) after a poor night's sleep.

Strongly disagree _____ Strongly agree
1 2 3 4 5

27. A "nightcap" before bedtime is a good solution to sleep problems.

Strongly disagree _____ Strongly agree
1 2 3 4 5

28. Medication is probably the only solution to sleeplessness.

Strongly disagree _____ Strongly agree
1 2 3 4 5

29. My sleep is getting worse all the time, and I don't believe anyone can help.

Strongly disagree _____ Strongly agree
1 2 3 4 5

30. It usually shows in my physical appearance when I haven't slept well.

Strongly disagree _____ Strongly agree
1 2 3 4 5

APPENDIX D

APPENDIX E

DIAGNOSTIC CRITERIA FOR SLEEP DISORDERS (DSM-IV TR, 2000)

DIAGNOSTIC CRITERIA FOR 347 NARCOLEPSY

Irresistible attacks of refreshing sleep that occur daily over at least 3 months

The presence of one or both of the following:

1. Cataplexy (i.e., brief episodes of sudden bilateral loss of muscle tone, most often in association with intense emotion)
2. Recurrent intrusions of elements of rapid eye movement (REM) sleep into the transition between sleep and wakefulness, as manifested by either hypnopompic or hypnagogic hallucinations or sleep paralysis at the beginning or end of sleep episodes
3. The disturbance is not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or another general medical condition

DIAGNOSTIC CRITERIA FOR 780.59 BREATHING RELATED SLEEP DISORDER

1. Sleep disruption, leading to excessive sleepiness or insomnia, that is judged to be due to a sleep-related breathing condition (e.g., obstructive or central sleep apnoea syndrome or central alveolar hypoventilation syndrome).
2. The disturbance is not better accounted for by another mental disorder and is not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or another general medical condition (other than a breathing-related disorder).

DIAGNOSTIC CRITERIA FOR 307.45 CIRCADIAN RHYTHM SLEEP DISORDER

1. A persistent or recurrent pattern of sleep disruption leading to excessive sleepiness or insomnia that is due to a mismatch between the sleep-wake schedule required by a person's environment and his or her circadian sleep-wake pattern.
2. The sleep disturbance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.
3. The disturbance does not occur exclusively during the course of another Sleep Disorder or other mental disorder.
4. The disturbance is not due to the direct physiological effects of a substance (e.g. a drug of abuse, a medication) or general medical condition.

Specify type:

Delayed Sleep Phase Type: A persistent pattern of late sleep onset and late awakening times, with an inability to fall asleep and awaken at a desired earlier time

Jet Lag Type: sleepiness and alertness that occur at an inappropriate time of day relative to local time, occurring after repeated travel across more than one time zone

Shift Work Type: insomnia during the major sleep period or excessive sleepiness during the major awake period associated with night shift work or frequently changing shift work.

Unspecified type

PARASOMNIAS

Parasomnias are disorders characterised by abnormal behavioural or physiological events occurring in association with sleep, specific sleep stages, or sleep-wake transitions. Parasomnias represent the activation of physiological systems at inappropriate times during the sleep-wake cycle. These disorders involve activation of the autonomic nervous system, motor system, or cognitive processes during sleep or sleep-wake transitions. Individuals with parasomnias usually present with complaints of unusual behaviour during sleep, rather than complaints of insomnia or excessive daytime sleepiness. This section includes Nightmare Disorder, Sleep Terror Disorder, Sleepwalking Disorder, and Parasomnia Not Otherwise Specified.

DIAGNOSTIC CRITERIA FOR 307.47 NIGHTMARE DISORDER

1. Repeated awakenings from the major sleep period or naps with detailed recall of extended and extremely frightening dreams, usually involving threats to survival, security, or self-esteem.
2. The awakenings generally occur during the second half of the sleep period.
3. On awakening from the frightening dreams, the person rapidly becomes oriented and alert (in contrast to the confusion and disorientation seen in Sleep Terror Disorder and some forms of epilepsy.)
4. The dream experience causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.
5. The nightmares do not occur exclusively during the course of another mental disorder (e.g., a delirium, Posttraumatic Stress Disorder) and are not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition.

DIAGNOSTIC CRITERIA FOR 307.46 SLEEP TERROR DISORDER

1. Recurrent episodes of abrupt awakening from sleep, usually occurring during the first third of the major sleep episode, and beginning with a panicky scream.
2. Intense fear and signs of autonomic arousal, such as tachycardia, rapid breathing, and sweating, during each episode.
3. Relative unresponsiveness to efforts of others to comfort the person during the episode.
4. No detailed dream is recalled and there is amnesia for the episode.
5. The episodes cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.
6. The disturbance is not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition.

DIAGNOSTIC CRITERIA FOR 307.46 SLEEPWALKING DISORDER

1. Repeated episodes of rising from bed during sleep and walking about, usually occurring during the first third of the major sleep episode.
2. While sleepwalking, the person has a blank, staring face, is relatively unresponsive to the efforts of others to communicate with him or her, and can be awakened only with great difficulty.
3. On awakening (either from the sleepwalking episode or the next morning), the person has amnesia for the episode.
4. Within several minutes after awakening from the sleepwalking episode, there is no impairment of mental activity or behaviour (although there may initially be a short period of confusion or disorientation).
5. The sleepwalking causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.
6. The disturbance is not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition.

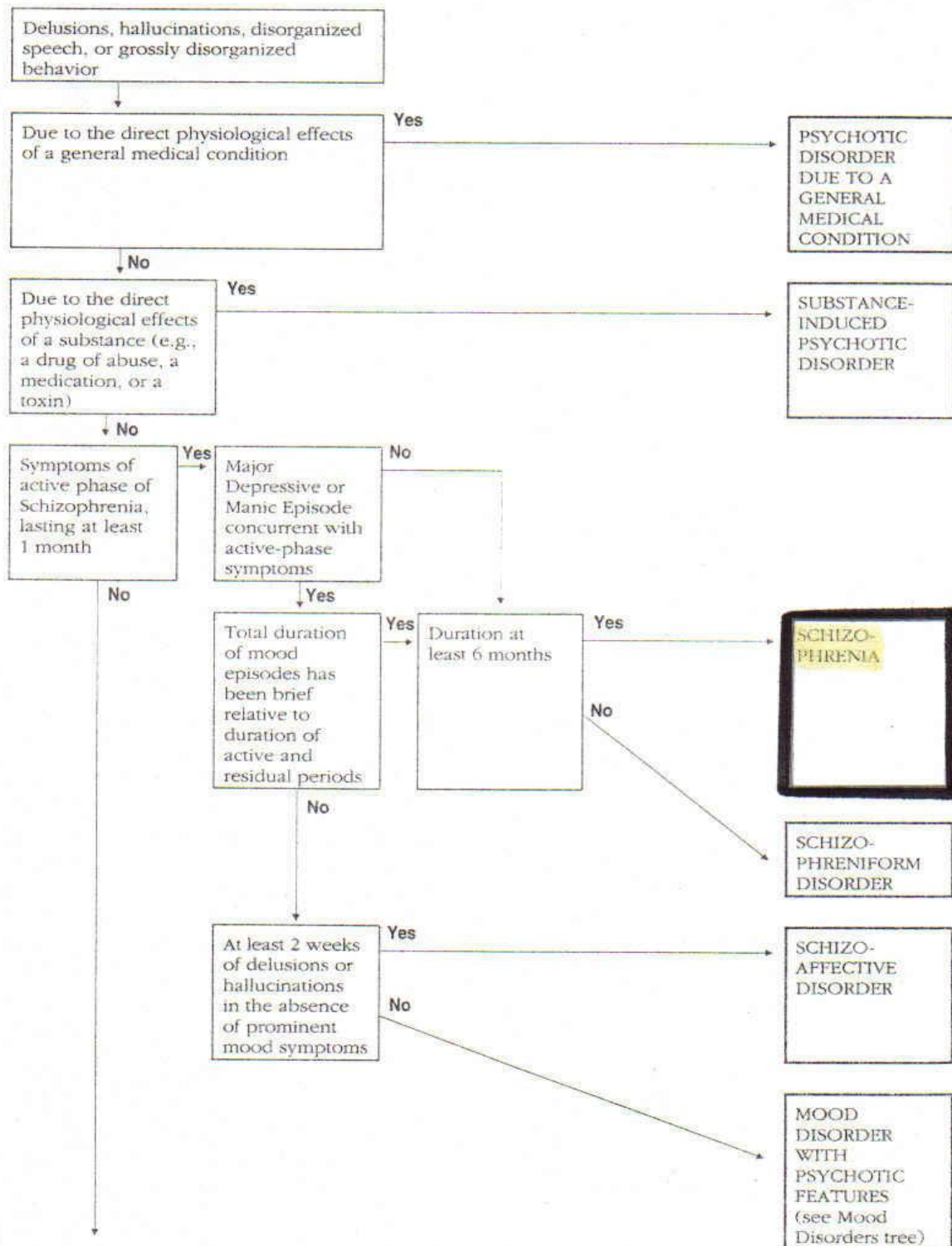
307.47 PARASOMNIA NOT OTHERWISE SPECIFIED

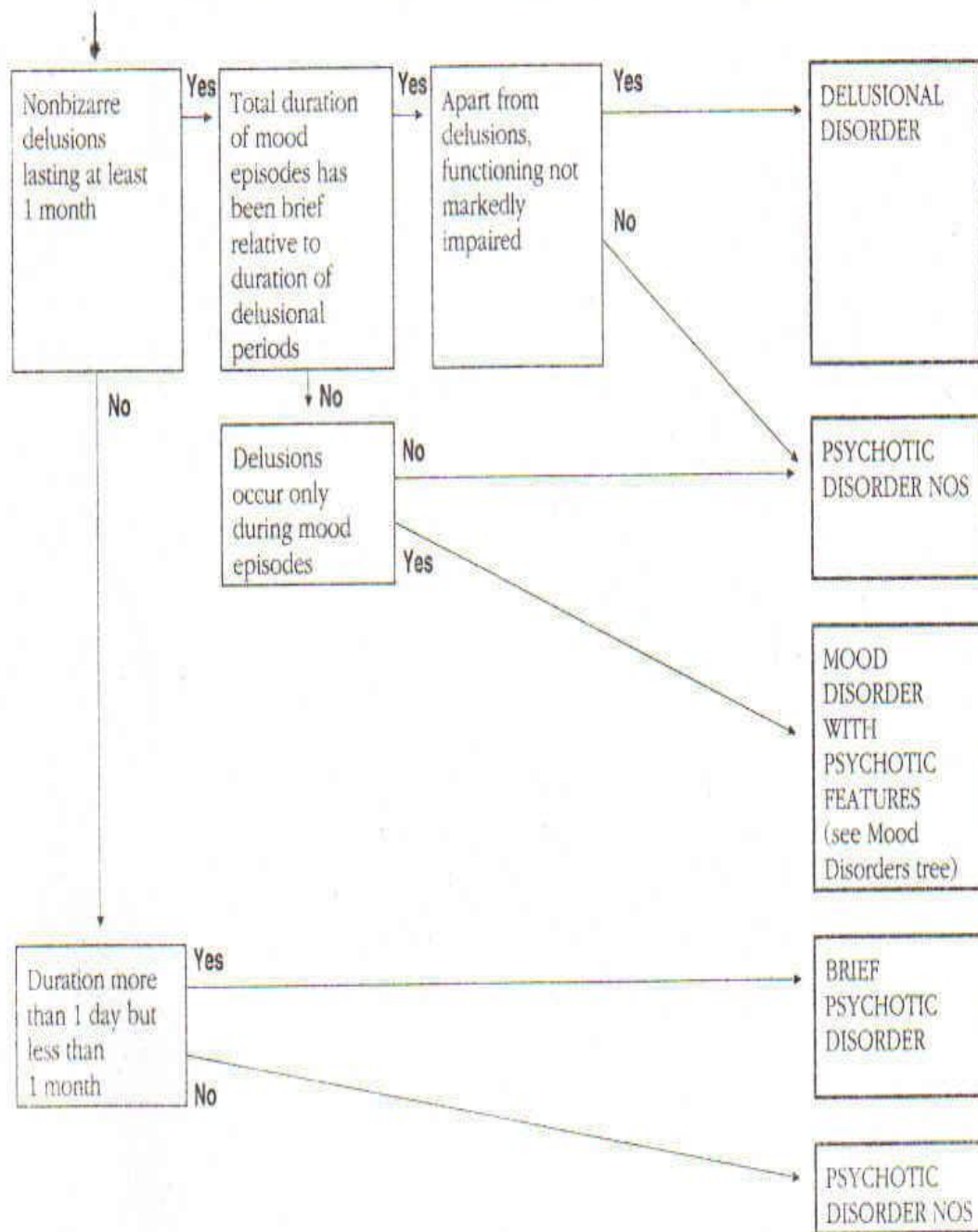
This category is for disturbances that are characterised by abnormal behavioural or physiological events during sleep or sleep-wake transitions, but that do not meet criteria for a more specific Parasomnia.

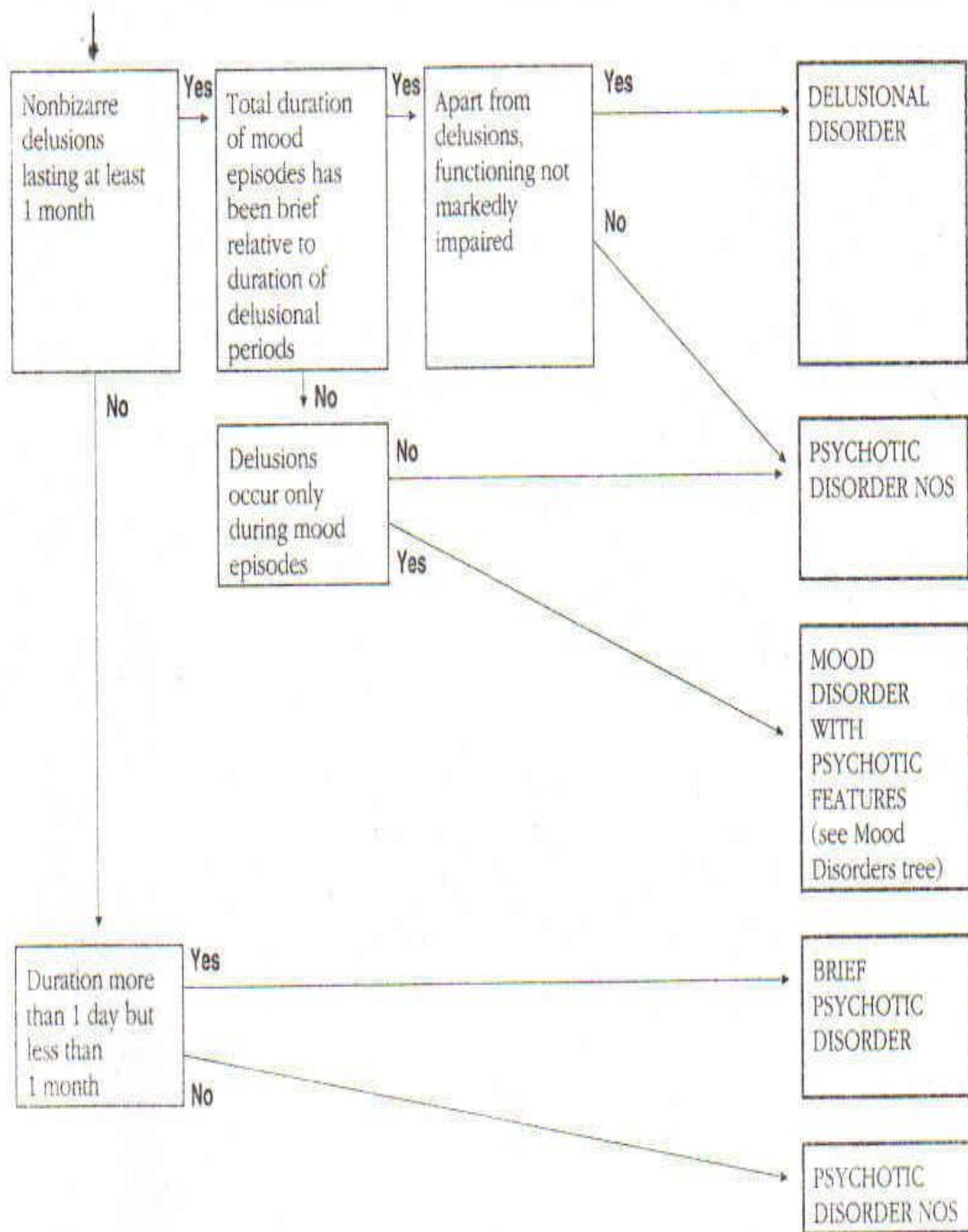
APPENDIX F

DIFFERENTIAL DIAGNOSIS OF PSYCHOTIC DISORDERS, MOOD DISORDERS AND ANXIETY DISORDERS (DSM-IV TR, 2000)

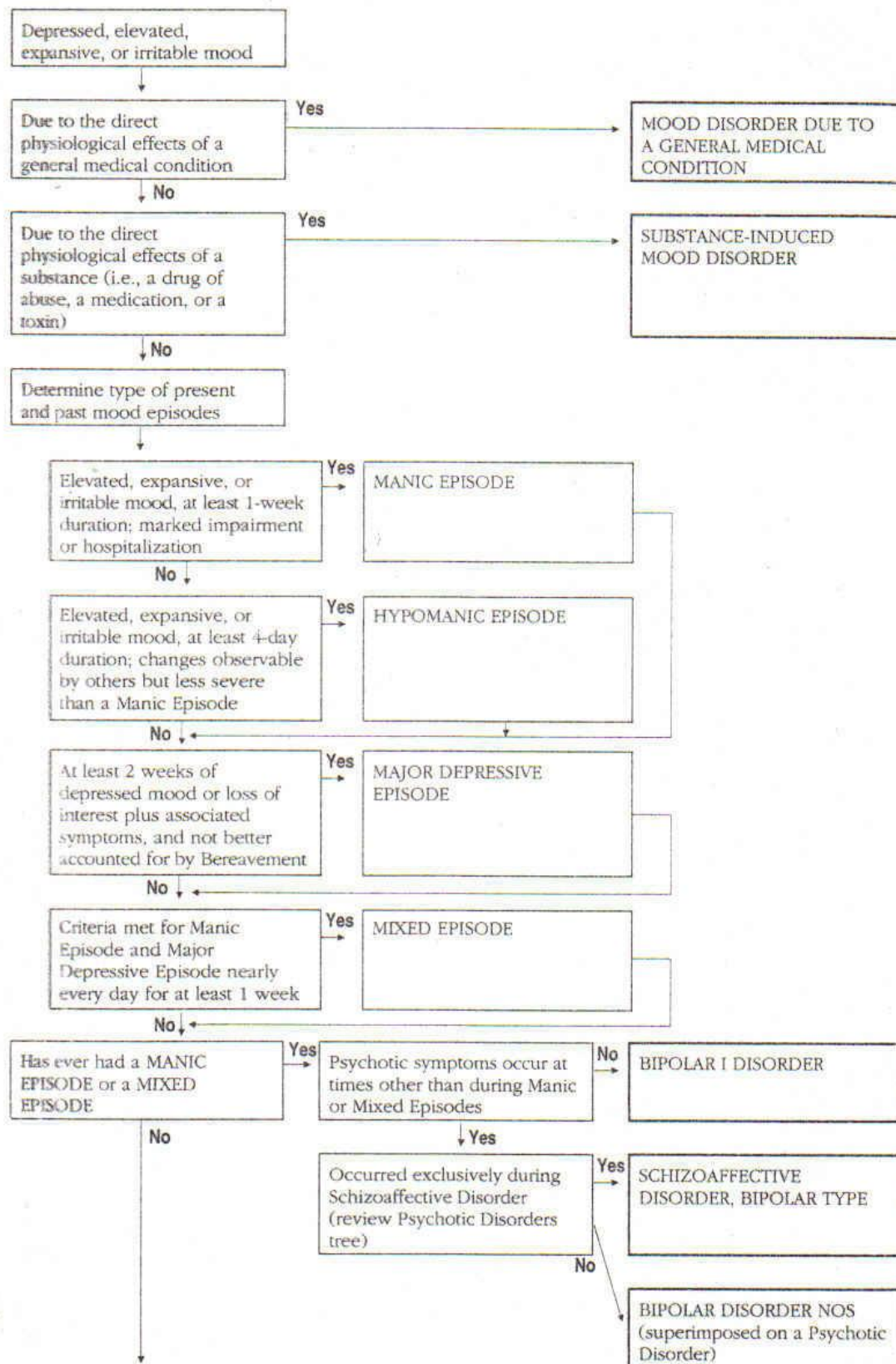
Differential Diagnosis of Psychotic Disorders



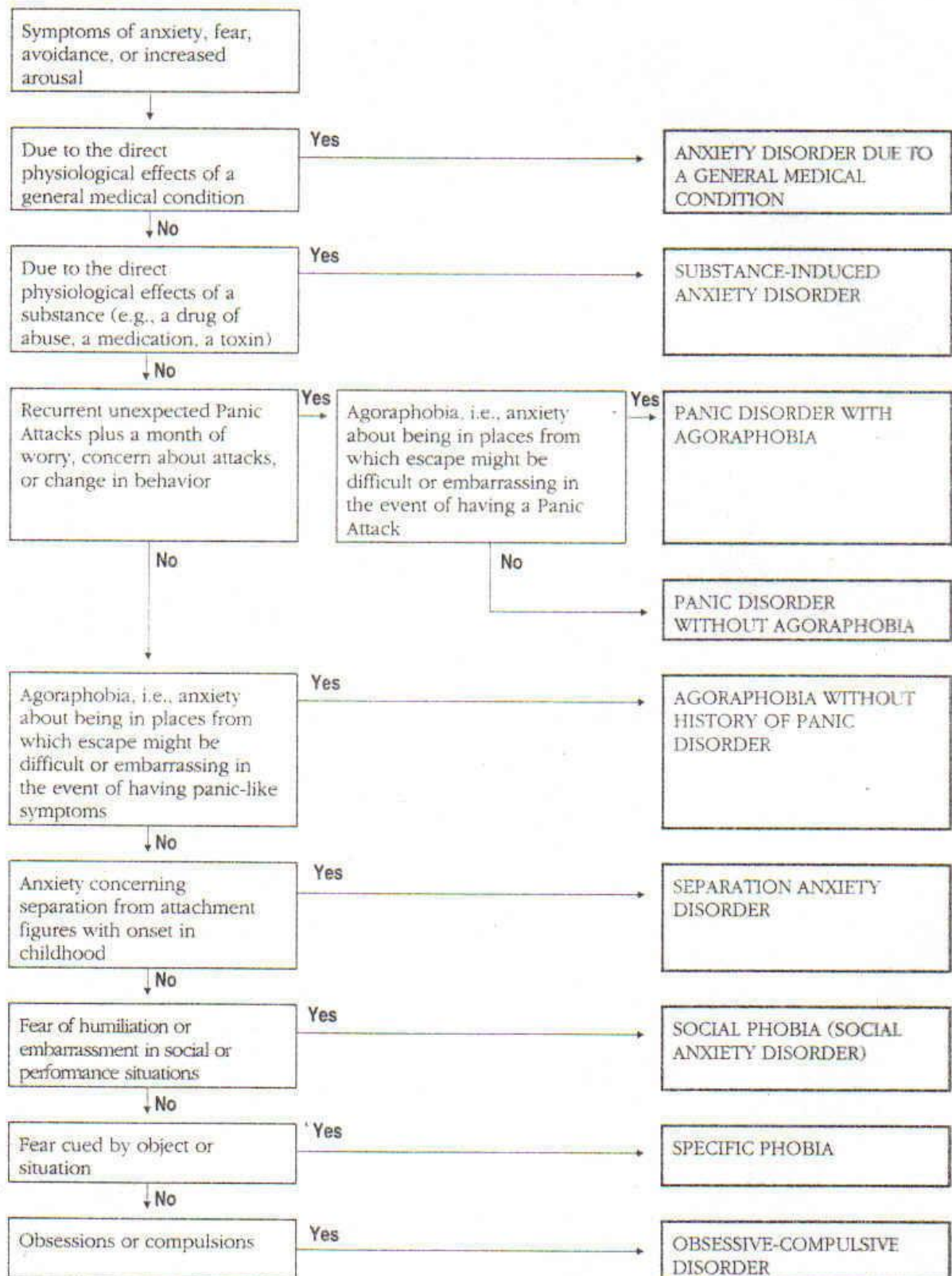


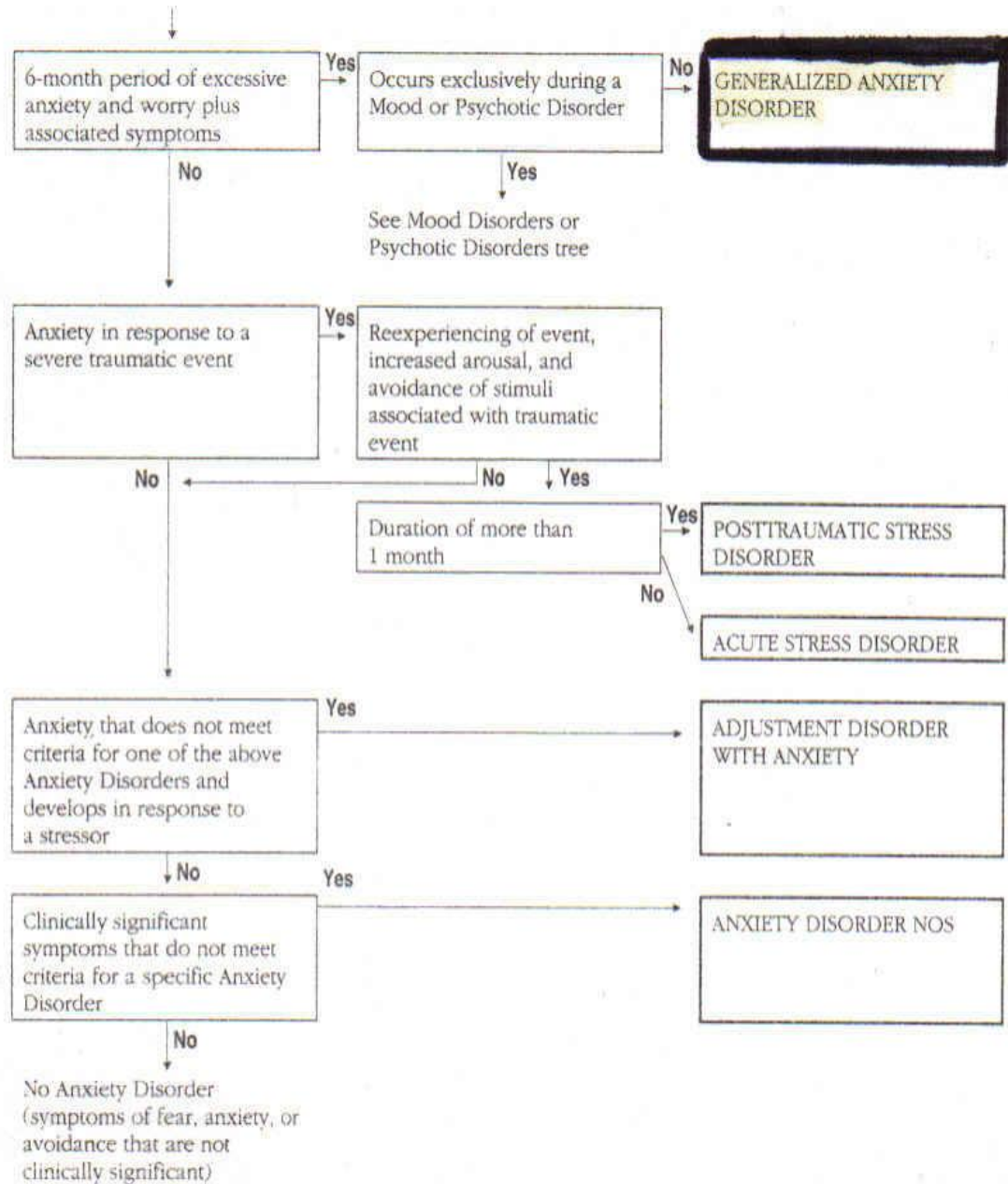


Differential Diagnosis of Mood Disorders



Differential Diagnosis of Anxiety Disorders





APPENDIX G



Edition of Sunday, January 23

HERALD

Bye-bye drowsiness - student offers help in beating sleepless night blues

April 18, 2004

By Herald Reporter

Restless and sleepless nights for some of the chronic insomnia sufferers of KwaZulu-Natal could soon be a thing of the past.

A final-year Durban Institute of Technology (DIT) homeopathic student, Ashnie Maharaj, is offering free homeopathic treatment for insomniacs. Maharaj, having completed her B Tech degree, is in her fifth year of study, and is conducting a probe into insomnia at the DIT as part of her masters degree research project. She is offering free consultations to about 30 participants.

Homeopathic remedies, she said, were tailored not only to the patient's symptoms, but also to their personality type and to the reason they became ill. "It involves delving into the depths of human nature, and the mental or emotional makeup of the patient.

"Homeopathy improves the patient's life on all levels.

"This is because homeopathy goes directly to the core of the person, to the body's own natural healing energy (the vital force), strengthening it and balancing it, so that not only the specific disease symptoms disappear, but the entire spiritual-mental-emotional-physical being is restored."

Chronic insomnia sufferers, she said, reported impairment in concentration and memory and difficulty in accomplishing tasks during the day.

"They have more difficulty in coping with minor irritations and report less enjoyment of family and social relationships. They also feel physically drained. Finally, they are twice as likely to report motor vehicle accidents in which fatigue was a factor."

Maharaj said many cases of insomnia had a fairly sudden onset at a time of psychological, social or medical stress.

"Primary insomnia often persists long after the original causative factors are resolved. It is associated with increased physiological, cognitive, or emotional arousal during the night, together with negative conditioning for sleep.

"There is a genetic predisposition towards disrupted sleep. Many insomniacs have a history of sleep difficulties," said Maharaj.

Other factors, she said, that may contribute to this condition include anxious over-concern with general health and increased sensitivity to the daytime consequences of sleep loss.

Maharaj said symptoms of anxiety or depression that did not meet the criteria for a specific mental disorder may be present.



"Primary insomnia typically begins in young adulthood or middle age and is rare in childhood or adolescence. Young adults complain of difficulty maintaining sleep and early morning awakening.

"Complaints of insomnia are prevalent with increasing age and among women. There are also suggestions that sleep problems are common in lower socio-economic classes," she said.

Insomnia sufferers seek treatment for insomnia mainly because of perceived distress or impairment, rather than how much sleep they get, she said.

"People with primary insomnia sometimes use medications inappropriately - hypnotics or alcohol to help with night-time sleep, anxiolytics to combat tension and anxiety, and caffeine or other stimulants to combat excessive fatigue.

"Chronic insomnia may induce emotional distress and increase the use of psychotropic medications and the risk of substance abuse and substance dependence.

"Adverse effects of excessive hypnotics intake include addiction, drowsiness, lethargy, hangover, and amnesia. Often skin eruptions and gastro-intestinal disturbances are side effects.

"Sudden withdrawal after prolonged use may precipitate severe tremors or seizures." said Maharaj.

She said those who qualified for treatment include those between 18 and 55 years of age. They must be literate, have taken no prescribed insomnia medication for at least one week before and during the study.

Those with the predominant complaint of difficulty initiating sleep, or non-restorative sleep for at least one month, qualified. The disturbances must not be due to the direct physiological effects of a substance (for example, drug abuse, medication), or a general medical condition.

Maharaj said those excluded included pregnant women, those suffering from narcolepsy, circadian rhythm sleep disorder or parasomnia.

Other participants who are excluded are those diagnosed with major depressive disorder, generalised anxiety disorder or schizophrenia, and those diagnosed with hyperthyroidism, hypertension, diabetes or hypercholesterolaemia.

To participate in the trial or for further information contact Ashnie Maharaj at 072 417 9722.

APPENDIX H

TELEPHONIC SCREENING INTERVIEW

I am a homoeopathy student at the Durban Institute of Technology. In order to qualify as a Homoeopath, a mini-dissertation has to be completed. This study will assess the effectiveness of homoeopathic treatment in alleviating insomnia.

How old are you?

How long have you had difficulty initiating or maintaining sleep?

How has this impacted on your life?

Have you taken any prescribed medication recently?

Have you been diagnosed with any chronic conditions? Explain?

If female: Are you pregnant?

Symptoms of other sleep disorders were queried:

Restless legs syndrome: Crawling or aching feelings in the legs (calves) and inability to keep legs still.

Periodic limb movements: Leg twitches or jerks during the night, waking up with cramps in the legs.

Sleep Apnea: Snoring, pauses in breathing at night, shortness of breath, choking at night; morning headaches, chest pain, dry mouth.

Narcolepsy: Sleep attacks, sleep paralysis, hallucinations.

Parasomnias: Nightmares, night terrors, sleepwalking/talking

Sleep-wake schedule disorder: Rotating shift or night shift work

Symptoms of Major Depressive Disorder, Generalised Anxiety Disorder and Schizophrenia will be queried (*Appendix F*)

Callers who fulfil the selection criteria and are willing to participate, will be asked to phone the Homoeopathic Day Clinic for appointment bookings.

APPENDIX I



SUBJECT INFORMATION LETTER

TITLE OF RESEARCH PROJECT:

The efficacy of homoeopathic simillimum in the treatment of chronic primary insomnia

NAME OF SUPERVISOR: Dr Ingrid Couchman (M. Tech. Hom)

NAME OF CO-SUPERVISOR: Dr David Naude (M.Tech. Hom)

NAME OF RESEARCH STUDENT: Ashnie Maharaj (5th year Homoeopathy student)

Date:

Dear Participant

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

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

This clinical trial will be conducted at the Homoeopathy Day Clinic during the afternoon sessions under the supervision of a qualified and registered homoeopath.

Each participant must comply with the selection criteria in order to participate in this study.

The study will include those that fulfil the following criteria:

1. Participants must be between the ages of 18 years to 70 years.
2. Participants must be literate.
3. Participants must have taken no other prescribed insomnia medication for at least one week before and during the study.
4. The predominant complaint is difficulty initiating or maintaining sleep, or nonrestorative sleep, for at least 1 month.
5. The sleep disturbance (or associated daytime fatigue) causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.
6. The disturbance is not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition.

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

1. Pregnant women
2. Participants suffering from Narcolepsy, a Breathing-Related Sleep Disorder, Circadian Rhythm Sleep Disorder, or a Parasomnia.
3. Participants diagnosed with Major Depressive Disorder, Generalised Anxiety Disorder or Schizophrenia
4. Participants diagnosed with hyperthyroidism, hypertension, diabetes and hypercholesterolaemia

If you fulfil the selection criteria, and are willing to participate, you will be accepted into the study group. This study will last for four weeks and the researcher will need to see you for two consultations during this time. At the consultations you will be required to fill in two questionnaires.

All information will be kept strictly confidential. Once the dissertation is published, the case files will be destroyed. Patient files will be kept in a locked drawer. Patients will be assigned a number and referred to as numbers only. No names will be mentioned in the dissertation. Confidentiality will be upheld at all times.

This study is a double-blind placebo controlled study. This means that 50% of patients will receive the active medicine, and the others will receive placebo. Placebo medication looks and tastes the same as the active medicine, but is neutral. Participants who receive placebo will receive free treatment at the end of the study. Treatment is available in the form of homoeopathic powders and will be dispensed by the homoeopathic clinic dispenser. All subjects may benefit with a relief of symptoms.

“Double blind” refers to the fact that neither the researcher nor the patients will know who is receiving what. This will only be known at the end of the data collection phase of the study, when the code is broken in order to analyse the data statistically.

Your participation in this study is on a voluntary basis and the consultation and treatment costs will be covered the Durban Institute of Technology. You are welcome to withdraw from this study at any time and without giving any reasons

If you have any questions about the study, please contact my supervisor or me.

Dr Ingrid Couchman: (031) 2042041

Ashnie Maharaj: 0724179722

Thank you for the courtesy of your assistance.

.....
ASHNIE MAHARAJ
(5th year Homoeopathy student)

APPENDIX J



INFORMED CONSENT FORM

TITLE OF RESEARCH PROJECT:

The efficacy of homoeopathic simillimum in the treatment of chronic primary insomnia

NAME OF SUPERVISOR: Dr Ingrid Couchman (M. Tech. Hom)

NAME OF CO-SUPERVISOR: Dr David Naude (M. Tech. Hom)

NAME OF RESEARCH STUDENT: Ashnie Maharaj (5th year Homoeopathy student)

PLEASE **CIRCLE** THE APPROPRIATE ANSWER

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

8. Do you understand that you are free to withdraw from this study? YES/NO

a) at any time

b) without having to give a reason for withdrawing, and

c) without affecting your future health care

9. Do you agree to voluntarily participate in this study? YES/NO

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

PATIENT NAME: _____ SIGNATURE: _____

WITNESS NAME: _____ SIGNATURE: _____

RESEARCH STUDENT NAME: _____

SIGNATURE: _____

APPENDIX K

RANDOMISATION SHEET (Compiled by Dr I Couchman on 29/03/04)

Patient number	Treatment	Placebo
1	X	
2	X	
3		X
4		X
5		X
6	X	
7		X
8	X	
9	X	
10		X
11		X
12	X	
13		X
14		X
15	X	
16	X	
17		X
18		X
19	X	
20	X	
21	X	
22		X
23		X
24		X
25	X	
26		X
27		X
28	X	
29	X	
30		X

APPENDIX L

CASE HISTORY QUESTIONNAIRE

(Bates, 1995)

DATE: _____ PATIENT NO.: _____

SURNAME: _____

FIRST NAMES: _____

AGE: _____ SEX: _____

OCCUPATION: _____

MARITAL STATUS: _____ CHILDREN: _____

ADDRESS: _____

TELEPHONE: _____

MAIN COMPLAINT: WHAT SEEMS TO BE THE PROBLEM?

HISTORY OF MAIN COMPLAINT: (Morin, 1993:195-198)

DO YOU HAVE A PROBLEM

- With falling asleep?
- With staying asleep?
- With waking up too early in the morning?
- With staying awake during the day?

CURRENT SLEEP-WAKE SCHEDULE:

What is your usual bedtime on weekdays?

At what time do you last awaken in the morning?

What is your usual arising time on weekdays?

Do you have the same sleep-wake schedule on weekends?

How often do you take naps (including unintentional naps)? (____days/week)

Do you ever fall asleep at inappropriate times/places?

How many nights/week do you have a problem with falling/staying asleep?

On a typical night (past month), how long does it take you to fall asleep after you go to bed and turn the lights off? (___hrs___mins)

On a typical night (past month), how many times do you wake up during the middle of the night?

What wakes you up at night? (Pain, noise, nocturia child, spontaneous)

On a typical night, how long do you spend awake in the middle of the night (total no. of minutes/hours for all awakenings)? ___hrs___mins)

How many hours of sleep per night do you usually get? (___ hrs ___mins)

SLEEPING AIDS:

In the past 4 weeks have you used sleeping pills?

Which drugs? Prescribed, over-the-counter, or both?

What dosage:

How many nights/week?

If no, have you ever?

When did you *first* use sleep medication?

When did you *last* use sleep medication?

In the past 4 weeks, have you used alcohol as a sleep aid?

What kind and how many litres?

How many nights/week?

If no, have you ever?

SLEEPING PROBLEM HISTORY (onset, course, duration):

How long have you been suffering from insomnia?

Were there any stressful life events related to its onset? (e.g. death of a loved one, divorce, retirement, medical or emotional problems, etc.)?

Gradual or sudden onset?

What has been the course of your insomnia problem since its onset (e.g. persistent, episodic, seasonal, etc.)?

BEDROOM ENVIRONMENT:

Are you sleeping with a bed partner?

Is your mattress comfortable?

Is your bedroom quiet?

Do you have a TV, radio, or phone in your bedroom?

Is there a desk with paperwork to be done in the bedroom?

Do you read in bed before bedtime?

What is your room temperature at night?

EATING, EXERCISE, AND SUBSTANCE USE HABITS:

How many times per week do you exercise?

Do you sometimes exercise prior to bedtime?

How many caffeinated beverages do you drink per day? After dinner?

Liquid intake in the evening?

FUNCTIONAL ANALYSIS:

What is your pre-bedtime routine like?

What do you do when you can't fall asleep or return to sleep?

Is your sleep better/worse/same when you go away from home?

Is your sleep better/worse/same on weekends?

What types of factors exacerbate your sleep problem (e.g., stress at work, travel plan, etc.)?

What types of factors improve sleep (e.g., vacation, sex, etc.)?

How concerned are you about sleep/insomnia?

What impact does insomnia have on your life (mood, alertness, and performance)?

How do you cope with these daytime sequelae?

Have you received treatment in the past other than sleep aids?

What prompted you to seek insomnia treatment at this time?

SYMPTOMS OF OTHER SLEEP DISORDERS:

Have you or your spouse ever noticed one of the following, and if so, how often on a typical week would you say you experience these symptoms?

- A. *Restless legs*: Crawling or aching feelings in the legs (calves) and inability to keep legs still.
- B. *Periodic limb movements*: Leg twitches or jerks during the night, waking up with cramps in the legs.
- C. *Apnea*: Snoring, pauses in breathing at night, shortness of breath, choking at night; morning headaches, chest pain, dry mouth.
- D. *Narcolepsy*: Sleep attacks, sleep paralysis, hallucinations
- E. *Parasomnias*: Nightmares, night terrors, sleepwalking/talking
- F. *Sleep-wake schedule disorder*: Rotating shift or night shift work

OTHER HISTORY:

PAST MEDICAL HISTORY:

(RHEUMATIC FEVER, PNEUMONIA, TUBERCULOSIS, JAUNDICE, HIGH BLOOD PRESSURE)

PAST SURGICAL HISTORY:

DID YOU HAVE ANY OPERATIONS SINCE YOU WERE BORN?

CHILDHOOD DISEASES/ILLNESSES:

(MUMPS, MEASLES, CHICKEN POX, GERMAN MEASLES, TUBERCULOSIS)

TONSILS:

ALLERGIES:

VACCINATION HISTORY:

FAMILY HISTORY:

(TB, DIABETES, HEART DISEASE, HYPERTENSION, STROKE, ASTHMA, ARTHRITIS, ANAEMIA, HEADACHES, EPILEPSY, ECZEMA, KIDNEY DISEASE, HAYFEVER, CANCER, MENTAL ILLNESSES)

MOTHER:

FATHER:

SIBLINGS:

GRANDPARENTS (MOTHER AND FATHER SIDE)

SOCIAL HISTORY:

1. WHAT ARE YOUR HOBBIES, LEISURE ACTIVITIES AND EXERCISE?

2. DO YOU SMOKE? HOW MANY?

5. DO YOU DRINK ALCOHOL?

HOW MUCH?

HOW OFTEN?

GENERALS:

ENERGY LEVELS

DREAMS

APPETITE

FOOD LIKES/DISLIKES

WEATHER LIKES/DISLIKES

THIRST

PERSPIRATION

SEXUAL LIBIDO

FEMALE MENSES

STDs

SUPPLEMENTS AND OTHER MEDICATIONS

SYSTEMS REVIEW:

HEAD:

HEADACHES – Types?

Location?

Frequency?

What makes it better/worse?

Associating symptoms?

EYES:

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

EARS:

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

NOSE AND SINUSES:

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

MOUTH AND THROAT:

(Swollen glands, pain or stiffness in the neck)

RESPIRATORY SYSTEM:

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

CARDIAC SYSTEM:

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

GATROINTESTINAL SYSTEM:

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

URINARY SYSTEM:

(Infection, burning and pain on urination)

GENITAL SYSTEM:

Female – menses

- discharge/leucorrhoea

Male – impotence

- sexual interest

MUSCULOSKELETAL SYSTEM:

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

NEUROLOGICAL SYSTEM:

(Numbness, paralysis, weakness, fainting, tumour)

ENDOCRINE SYSTEM:

(Thyroid trouble, diabetes)

ON EXAMINATION:

VITAL SIGNS:

PULSE

BLOOD PRESSURE

RESPIRATORY RATE

TEMPERATURE

WEIGHT AND HEIGHT

GENERAL OBSERVATION:

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

HEAD: inspection and palpation

Note any – Deformities or lumps
- Tenderness, other lesions

FACE: inspection and palpation

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

EYES: inspection and palpation

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

NOSE AND PARANASAL SINUSES:

Inspection and palpation

Examine external and internal surface
Palpate the sinuses – Frontal sinus tenderness
Maxillary sinus tenderness
Postnasal drip – colour, odour, quantity, frequency

MOUTH AND PHARYNX:

Lips – colour, moisture, swelling
Mouth – breath, taste, pain, lesions
Teeth – caries, pain, abnormalities in shape, colour and position
Pharynx – tonsils, swellings, lesions, colour, ulceration, uvula

EARS:

Inspection and palpation

Ear drum and canal - Discharge, foreign bodies, redness and swelling, serum, colour and contour

- Handle of malleus
- Cone of light
- Perforations

NECK:

Inspection and palpation

Stiffness and pain
Thyroid gland
Tracheal deviation
JVP
Lymph nodes

THORAX:

Inspection and palpation

Chest wall movement and shape

Auscultation of heart and lungs

ABDOMEN:

Inspection

Palpation: Pain, tenderness, guarding, spleen, liver, kidneys.

Auscultation

BACK:

Inspection: Symmetry of body

Curvature and orientation of spine

Posture, any restricted movements

Auscultation

UPPER AND LOWER LIMBS:

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

AXILLAE:

Inspection

Palpation: 4 areas – Central – Deep

Distal

Pectoral/anterior

Subscapular/posterior

As well as – Supraclavicular

Infraclavicular

APPENDIX M



SLEEP SOCIETY OF SOUTH AFRICA SLAAPVEREENIGING VAN SUID-AFRIKA

DEPARTMENT OF PHYSIOLOGY - UNIVERSITY OF THE WITWATERSRAND
MEDICAL SCHOOL, 7 YORK ROAD, PARKTOWN, JOHANNESBURG

SLEEP HYGIENE RULES

a. Stick to a regular bedtime and wake up time. Waking at a regular time every morning maintains a correct bedtime and stops the excess sleeping in at weekends which may itself result in problems falling asleep the next night.

b. Reduce the amount of smoking, alcohol and caffeine that you take in during the day. Don't take any of these within 3 hours of sleeping at the very least. If a strong cup of coffee makes your hands shake you should not consume any caffeine at all during the day.

c. Do not spend more than 15 minutes trying to fall asleep. It doesn't matter whether this is initially when you go to sleep or during the night. Don't watch the clock while trying to fall asleep but rather check after a short period and if 15 minutes has gone by then get up. Get out of bed and do something else. This could be cleaning cupboards, watching TV or reading. Continue doing this activity for up to 60 minutes or until you feel sleepy again.

Then you may go back to bed and try again. The 15-minute rule still applies. You may very well spend the first night doing only this or else fall asleep at 4 am – just before you need to get up. You must get up at the correct time.

The important thing to focus on is the success you had at falling asleep within the 15 minutes – the actual time of falling asleep is not important. Once you have fallen asleep within 15 minutes you will start to believe that it can be done. This will start to reverse the attitude that you are unable to fall asleep at all but rather that you are able to fall asleep at 4 am within 15 minutes.

It is simply a matter of time before the ability to fall asleep at 4 am becomes a belief in being able to fall asleep at 3 am, then at 2 am and so on. The next night you will probably fall asleep earlier.

If you use these hygiene rules with a sleep restriction program and a sleep diary there is usually an improvement over the next 10-14 nights. Your ability to fall asleep when sleepy- even if it is later than normal – should be vastly improved.

Sometimes you may need to use a sleeping medication to help you through this process. The best way to take the medication is every third night no matter how you are sleeping. Keep the timing and the other rules the same but look forward to the good nights sleep every third night. You will feel less desperate and you will not get dependent on the medication if you only take it for a few weeks in this way.

APPENDIX N

METHOD 10: Granules (Globuli) (British Homoeopathic Association, 1991)

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

Following impregnation in a closed vessel, the granules (globuli) are air-dried. They are labeled with the dilution stage of the dilution used to impregnate them.

The following granule sizes may be used in special cases:

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

