The efficacy of a homoeopathic complex (*Nux moschata* D6, *Phosphoricum acidum* D30, *Helleborus niger* D6, *Opium* D30) in the management of Excessive Daytime Sleepiness.

By

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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 University of Technology

Supervisor: Dr D.F. Naude

Date: January 2018

DECLARATION

This is to certify that the work is entirely my own and not of any other person, unless explicitly acknowledged (including citation of published and unpublished sources). The work has not previously been submitted in any form to the Durban University of Technology or to any other institution for assessment or for any other purpose.

The research described in this dissertation was supervised by: Dr D.F. NAUDE – Senior lecturer Department of Homoeopathy, Faculty of Health Sciences, Durban University of Technology, Durban, South Africa.

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Dr D. F. Naude

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DEDICATION

To the Lord God Almighty, The King of Glory ‘Jesus Christ’

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I would like to acknowledge and extend the most gratitude to the following people, who made all of this work possible:

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To all my patients who participated

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ABSTRACT

BACKGROUND

Excessive daytime sleepiness (EDS) is the inclination or compulsion to fall asleep whilst intending to stay awake; it is believed to negatively affect occupational and social functioning and may be a predisposition towards accidents (Hayley et al. 2014), low productivity and interpersonal problems (Fong et al. 2005).

Excessive daytime sleepiness is one of the most common sleep-related symptoms and it affects an estimated 20% of the population (Pagel .2009). The causes of EDS are numerous and include intrinsic sleep disorders (e.g. narcolepsy, obstructive apnoea/ hypopnea syndrome, idiopathic hypersomnia), and extrinsic disorders (Banerjee et al. 2004). Sleep deprivation is probably the most common cause of excessive daytime sleepiness.

This clinic trial intended to evaluate the effectiveness of a homoeopathic complex (Nux moschata D6, Phosphoricum acidum D30, Helliborus niger D6, Opium D30) in the management of EDS in terms of the Epworth Sleepiness Scale (Johns, 1991) and Stanford Sleepiness Scale (Hoddes et al. 1973). And this randomised, double-blind placebo controlled study also aimed to provide a safe and effective alternative therapy for EDS.

AIM OF THE STUDY

The objective of this study was to determine the efficacy of a homoeopathic complex (Nux moschata D6, Phosphoricum acidum D30, Helliborus niger D6, Opium D30) and placebo in the management of EDS in terms of the Epworth Sleepiness Scale (ESS) and the Stanford Sleepiness Scale (SSS).

MATERIALS AND METHODOLOGY

A sample group of 35 participants was selected voluntarily to conduct the study on basis of the inclusion and exclusion criteria. The participants were than randomly divided into two groups; a treatment group consisting of 23 participants and a placebo group consisting of 12 participants. Each participant had to attend three consultations in total with the researcher over a period of four weeks at the Durban University of Technology (DUT) Homoeopathic Day Clinic.

At the first consultation a comprehensive case history (appendix F) was taken and physical examination (appendix E) was performed by the researcher but no medication was handed at that point. At each consultation the participants with the help of the researcher completed the Epworth Sleepiness Scale (ESS), and the seven days' baseline Stanford Sleepiness Scale (SSS) was handed to the participants at the first and second consultation which the participants completed without the help of the researcher throughout the trial till their last consultation.

RESULTS

Results from the two measuring tools were statistically analysed with SPSS version 24.0. the participant's level of sleepiness improved in both the treatment group and the placebo group.

Intra-group analyses of ESS means revealed that both groups improved significantly over time, intergroup ANOVA analysis however revealed no significant differences between the groups. Section analyses however using the Fisher's Exact Tests did reveal statistically significant differences within certain variables at some points of the study.

Intra-group analyses of SSS data revealed no statistically significant change in SSS scores over the three weeks in both the Homoeopathic Complex and the Placebo Groups, as well as the Inter-group Fischer's Exact tests revealed no statistically significant differences between the groups.

CONCLUSION

Barring a few exceptions described in Chapter 4 & 5 it can be concluded from the results of the study that statistically the Homoeopathic complex (Nux moschata D6, Phosphoricum acidum D30, Helliborus niger D6, Opium D30) was not superior to placebo in the treatment of EDS. The data shows that both the Homoeopathic Complex and the placebo interventions had a positive effect on EDS and were effective in improving the level of excessive daytime Sleepiness. Irrespective of the general lack of statistical significance between groups a closer analysis of the intragroup and inter-group data does reveal a trend suggesting clinical significance in support of the effectiveness of the homoeopathic complex in the treatment of EDS however this needs to be further explored and confirmed in subsequent studies.

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LIST OF ABBREVIATIONS:

1.EDS – Excessive Daytime Sleepiness

2.ESS – Epworth Sleepiness Scale

3.SSS – Stanford Sleepiness Scale

4.CAM –Complementary Alternative Medicine

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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).

Allopathy

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

Complementary remedy

This is a term used to describe a remedy which assists another remedy in its action (Yasgur 1997:54).

Excessive Daytime Sleepiness (EDS)

Excessive daytime sleepiness (EDS) is the inclination or compulsion to fall sleep whilst intending to stay awake; it is believed to negatively affect occupational and social functioning and may be a predisposition toward accidents (Hayley et al. 2014), low productivity and interpersonal problems (Fong et al. 2005).

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 Complex

A homeopathic preparation containing more than one medicinal substance (Gaier, 1991).

Homoeopathic drug preparation

According to (Gaier 1991), 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.

Insufficient Sleep syndrome

Group of symptoms that lead to changes in sleeping habits (Thorpy 2016).

Law of Similars

A principle of Homoeopathic medicine stating that a drug capable of producing morbid symptoms in a healthy person will cure similar symptoms occurring as a manifestation of disease. (Stedman's Medical Dictionary 2002)

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).

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).

Potency

The word "potency" has the connotation of power. The nearest analogy would be "strength." Potency in many ways is the homoeopathic equivalent to dosage (Leckridge, 1997). which promotes restoration of health (O'Reilly, 2001).

Potentisation

A multi-step process (involving dilution and succussion or trituration) by which the inner medicinal power of a crude substance is released (O'Reilly, 1996).

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.

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 et al. 1994)

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).

Qualitative analysis

The non-numerical examination and interpretation of observations for the purpose of discovering underlying meanings and patterns of relationships (Silverman, D.1997:

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).

Remedy

A means for the cure of a disease or other disorder of body, mind or spirit; any medicine or treatment

Repertory

This is a systematic cross reference of symptoms and disorders to various homoeopathic medicines in whose therapeutic repertoire they occur (Swayne, 2000:183).

Sleep hygiene

Sleep hygiene is a variety of different practices that are necessary to have normal, quality night time sleep and full daytime alertness (Thorpy, 2016).

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).

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 motar (Gaier, 1991: 559).

The Epworth Sleepiness Scale (ESS)

An inexpensive, easy to administer quantitative measurement tool used to determine the level of daytime sleepiness in which. the client self-rates on how likely it is that they would doze in eight different situations (Johns 1991).

The Stanford Sleepiness Scale (SSS)

The most broadly used and time efficient subjective measure of sleepiness administered at 2 hour intervals during the day (Shahid, 2010) which consists of a 7point scale of equal intervals starting from 1 (being very alert) to 7 (being excessive sleepy) (Herscovitch & Broughton 1981).

Treatment Group

The group of subjects in a clinical trial who receives treatment that is specific for a given condition (Bloch, 2002)

CHAPTER ONE

OVERVIEW OF THE STUDY

1.1 THE CONTEXT OF THE STUDY

Homoeopathy is a natural system of treatment which aims to maintain equilibrium both within the body (homeostasis) and in the entire ecosystem (Chauhan et al., 2007). Homoeopathic philosophy is based on the Law of Similars; an organism under stress typically reacts by producing a unique set of signs and symptoms, these signs and symptoms act like individualistic clues to the homoeopath based on which the indicated corresponding medication is individually selected; the remedy choice is based on the principle of “Similia Similibus Curentur” (Chauhan et al., 2007). This principle dictates that the remedy must have the ability to produce symptoms that are most similar to the disease to be cured in a healthy individual (Chauhan et al., 2007). In homoeopathy, the life force or vital force is a force, power or energy that enlivens the material organism (O’Reilly, 1996); this immaterial being carries out all the functions of life and without this energy the material organism is capable of no sensation, function or self-preservation (Chauhan et al., 2007) it is the ‘vital force’ on which homoeopathic remedies act. Homoeopathy being a therapeutic method based on the law of similars, thus the name, derived from the Greek word “homoios” meaning similar and “pathos” meaning pain of suffering (Eizayaga, 1991). The law of similar states that a medicine which produces a group of symptoms in a healthy person is able to cure those very symptoms if presented in a diseased person, (Eizayaga, 1991).

Homoeopathic complexes are considered to be a pragmatic, convenient form of homoeopathic prescribing; such formulations comprise multiple ingredients each of which address various symptoms of the same condition simultaneously, prescribing a homoeopathic complex is thought to increase the change of the correct prescription for a specific condition (Kayne, 2006)

According to Coppola and Montanaro (2013) homoeopathic complex medicine may provide favourable effects with a good safety profile, in the absence of concomitant therapies. The use of homoeopathic medicines to prevent different diseases should

be encouraged in the public health system considering that homoeopathy is a safe and low-cost and effective therapy (Coppola and Montanaro 2013).

According to the international classification of sleep disorders (2005) daytime sleepiness is defined as a condition that causes difficulty in maintaining the alert awake state during the wake phase of the 24 hour sleep-wake cycle (Tetyana et al. 2013).Excessive Day time Sleepiness is a significant aspect of sleep medicine (Hayley et al. 2004) and is highly prevalent in community and patient populations (Bailes et al. 2006) most studies sourced reporting a prevalence greater than 10% (Joo et al. 2009) (Hayley et al. 2014). This condition has potential serious outcomes; it is believed to negatively affect occupational and social functioning and may be a predisposition toward accidents (Hayley et al. 2014), low productivity and interpersonal problems (Fong et al. 2005).

Traditional methods of pharmacotherapy such as psychostimulants used to increase alertness are associated with negative side-effects such as nervousness, irritability, headaches, tachycardia, mood changes and tremor; other concerning side-effects include psychiatric complications and potential liver toxicity. The risk of abuse, particularly of sympathomimetic psychostimulants is well known; being classified as having a ‘high potential for abuse which may lead to severe psychological or physical dependence’ (Banerjee et al. 2004).

The specific homoeopathic remedies chosen for this homoeopathic complex are all well-established; existing remedies used in general clinical practice; each of which is clinically indicated for the signs and symptoms of EDS. Nux moschata is indicated typically for conditions associated with drowsiness or dreamy states with vanishing thoughts as well as sleepy attacks accompanied by heaviness of the eyes Banerjee (Phatak 1982). Phosphoricum acidum is indicated for conditions characterised by debility and nervous exhaustion with mental debility followed by physical debility in those who are overtaxed mentally or physically (Boericke 1994). Helliborus niger is indicated for conditions where the brain and mind senses are diminished and responses sluggish, typically indicated for inattentiveness, dullness and apathy and thoughtless staring (Phatak 1982). Opium is indicated for states of drowsy stupor, torpidity and sluggishness of function with loss of power and concentration (Phatak 1982).

It was anticipated that a combination of these well-known homoeopathic remedies based on the respective correlations between their clinical indications and that of the signs and symptoms of EDS (in accordance with the Homoeopathic Law of Similars) would be an effective homoeopathic intervention which broad spectrum sphere of action.

1.2 AIM AND OBJECTIVES OF THE STUDY

1.2.1 AIM:

The aim of this randomised, double-blind placebo controlled study was to determine the efficacy of a homoeopathic complex (Nux moschata D6, Phosphoricum acidum D30, Helliborus niger D6, Opium D30) in the management of EDS in terms of the Epworth Sleepiness Scale (Johns, 1991) and Stanford Sleepiness Scale (Hoddes et al. 1973).

1.2.2 OBJECTIVE ONE:

To determine the efficacy of a homoeopathic complex in the management of EDS in terms of the Epworth Sleepiness Scale (ESS).

1.2.3 OBJECTIVE TWO:

To determine the efficacy of a homoeopathic complex in the management of EDS in terms of the Stanford Sleepiness Scale (SSS).

CHAPTER TWO

REVIEW OF RELATED LITERATURE

2.1. SLEEP PHYSIOLOGY

Sleep is defined as unconsciousness from which the person can be aroused by sensory or other stimuli (Guyton and Hall, 2011). 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 et al, 2003)

Table 2.1 The stages of sleep cycle (Beers et al, 2003)

Stage 1	**Stage 2**	**Stage 3**	**Stage 4**	**Stage 5**
4-5% Light sleep, muscle activity slows down. Occasional muscle twitching.	45-55% Breathing pattern and heart rate slows. Slight decrease in body temperature.	4-6% Deep sleep begins. Brain begins to generate slow delta waves.	12-15% Very deep sleep. Rhythmic breathing. Limited muscle activity. Brain produces delta waves.	20-25% Rapid eye movement. Brain waves speed up and dreaming occurs. Muscles relax and heart rate increases. Breathing is rapid and shallow.

Table 2.1 describes the different sleep cycle stages (from stage 1 to 5).

2.1.1 (Non-Rapid Eye Movement) NREM SLEEP

NREM sleep is dreamless sleep. During NREM, the brain waves on the electroencephalographic (EEG) recording are typically slow and of high voltage, the breathing and heart rate are slow and irregular, the blood pressure is low, and the sleeper is relatively still (Guyton at el., 2003).

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 (Guyton at el. 2003). There is slow rolling of the eyes and 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 at el. 2003).

In stage 2 eye movements becomes rare and EMG activity 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 et al, 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 et al., 2003).

2.1.2 (Rapid Eye Movement) REM SLEEP

According to Guyton and Hall (2003), 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.

The 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 et al. 2011).

2.2 CLASSIFICATION OF SLEEP DISORDERS

According to the DSM-V TR (2013), 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.

2.2.1 Primary sleep disorders

Primary sleep disorders are classified in the following manner:

2.2.1.1 Dyssomnias which include:

- Primary insomnia
- Primary hypersomnia
- Narcolepsy
- Breathing-related sleep disorder
- Circadian rhythm sleep disorder and
- Dyssomnias not otherwise specified

2.2.1.2 Parasomnias which include:

- Nightmare disorder
- Sleep terror disorder
- Sleepwalking disorder and
- Parasomnia not otherwise specified

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- Sleepwalking disorder and
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2.2.1.1 Dyssomnias

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 (DSM-V TR 2013).

Primary Hypersomnia

According to (Plate 2015) also called hyper somnolence or sometimes idiopathic hypersomnia (meaning that it arises from no known cause), primary hypersomnia is a sleep disorder characterized by excessive daytime sleepiness, excessive sleep periods each day (usually taken to mean more than 10 hours) and/or an inability to achieve the feeling of refreshment that sleep usually brings (Plate 2015). Chronic sufferers may sleep up to 18 hours a day or more and still not feel refreshed upon waking. The disorder usually develops slowly over a period of years, typically starting in late adolescence, when it is often confused with normal teenage sleep issues like delayed sleep phase syndrome (Plate 2015). 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.

Narcolepsy

According to (Sureshbabu 2016) narcolepsy is a neurological disorder characterized by the brain's inability to control sleep/wakefulness cycles. People with narcolepsy suffer from chronic daytime sleepiness and episodes in which they fall asleep unexpectedly during the day (Sureshbabu 2016), these "sleep attacks" can occur at

any time, during any activity. Sleep attacks are not limited to periods of dull or low engagement activities, but can happen during school or work hours, in the middle of a conversation, while eating, while exercising or playing sports, or most dangerously– while driving (Sureshbabu 2016).

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 (DSM-V TR 2013).

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) (DSM-V TR 2013).

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 (DSM-V TR 2013).

Dyssomnias Not Otherwise Specified

This category is for insomnias, hypersomnias or circadian rhythm disturbances that do not meet criteria for any specific dyssomnia (DSM-V TR 2013).

2.2.1.2 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 (DSM-V TR 2013).

This section includes:

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.) (DSM-V TR 2013).

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 (DSM-V TR 2013).

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 (DSM-V TR 2013).

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 (DSM-V TR 2013).

2.2.2 Other type of sleep disorders:

Sleep Apnoea:

When you have this condition, your breath can become very shallow or you may even stop breathing briefly while you sleep. It can happen many times a night in some people (DSM-V TR 2013).

Obstructive sleep apnoea:

Happens when something partly or completely blocks your upper airway during shuteye. That makes your diaphragm and chest muscles work harder to open the obstructed airway and pull air into the lungs. Breathing usually resumes with a loud gasp, snort, or body jerk. You may not sleep well, but you probably won't be aware that this is happening. The condition can also reduce the flow of oxygen to vital organs and cause irregular heart rhythms (DSM-V TR 2013).

Idiopathic hypersomnia:

According to (Masri et al 2015) Idiopathic hypersomnia is a sleep disorder in which a person is excessively sleepy (hypersomnia) during the day and has great difficulty being awakened from sleep. Idiopathic means there is not a clear cause.

2.2.3 Sleep Disorder due to a General Medical Condition

This involves sleep disturbances resulting from the direct physiological effects of a general medical condition (DSM IV, 2013).

2.2.4 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. (DSM IV, 2013)

2.2.5 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. (DSM, 2013).

2.3 EXCESSIVE DAYTIME SLEEPINESS

2.3.1 Definition

Excessive daytime sleepiness (EDS) is the inclination or compulsion to fall sleep whilst intending to stay awake; it is believed to negatively affect occupational and social functioning and may be a predisposition toward accidents (Hayley et al. 2014), low productivity and interpersonal problems (Fong et al. 2005). According to the international classification of sleep disorders (2005) daytime sleepiness is defined as a condition that causes difficulty in maintaining the alert awake state during the wake phase of the 24-hour sleep-wake cycle (Tetyana et al. 2013). According to Kumar et al. (2002) EDS became a symptom of concern for the treating physician due to its direct impact on road safety and in public health.

2.3.2 Aetiology

According to (Banerjee et al. 2004), causes of EDS are numerous and include intrinsic sleep disorders (e.g. narcolepsy, obstructive apnea/ hypopnea syndrome, idiopathic hypersomnia), and extrinsic disorders. Sleep deprivation is probably the most common cause of excessive daytime sleepiness. Studies that restricted healthy adults to six hours of sleep per night for 14 successive nights showed a cumulative significant impairment of neurobiological function, also the persons who are chronically sleep deprived are often unaware of their increasing cognitive and performance deficits (Banerjee et al. 2004).

2.3.3 Signs and Symptoms

The signs and symptoms of this condition are; lack of concentration, extreme tiredness, lack of engagement of strenuous activities and an inability to remain alert even when they were previously alert. Prevalence is found to be high in women than in men but the more during the middle age (50-59 years) and ages above 80 years. (Hayley et al. 2014).

EDS is also associated with compromised professional performance, reduced cognitive function, this can affect the ability to gain or maintain employment, because these patients may be misperceived as lazy or unmotivated, (Pagel, 2009).

2.3.4 Risk Factors and Impact of EDS

According to (Pagel .2009), excessive daytime sleepiness is one of the most common sleep-related symptoms and it affects an estimated 20% of the population. Persons with excessive daytime sleepiness are at risk of motor vehicle and work related incidents, and have poorer health than comparable adults. The sleep problems contribute to more than 100 000 motor vehicle incidents that result in more than 71 000 personal injuries and 1500 deaths annually. Up to 52% of single vehicles crashes involving heavy trucks are fatigue related, with the driver falling asleep in 17.6% of cases. Most sleep related crashes involve adolescence and young male adult drivers (Pagel, 2009).

2.3.5 Incidence and Prevalence

About 20% of adults in the United States report a level of daytime sleepiness sufficient to interfere with daily activities and excessive daytime sleepiness is the leading symptom of patients presenting to sleep clinics. The prevalence of EDS is highest in adolescence, older persons and shift workers, (Pagel 2009).

There appears to be a particular prevalence amongst adolescents and young adults; sleepy adolescents have significantly lower levels of academic performance, increased school tardiness and lower graduation rates than other students, (Pagel, 2009).The prevalence of EDS amongst university students has been well documented; Tsou (2013) reported a prevalence of 27% amongst students from two Taiwanese universities and established an association between EDS and emotional disturbances similarly high prevalence rates have been reported amongst university students in Peru (35%), 28% (Chile), 26% (Ethiopia) and 27% (Taiwan) (Whittier et al. 2013; Concepcion et al. 2013; Robinson et al. 2013, Tran et

Existing literature too reports a higher prevalence amongst females than males; (Hayley et al. 2014) reported prevalence of EDS in Australians of similar age range (20-29yrs) to be 5.1% male and 14.7% in females and according to (Joo et al. 2009) the prevalence of EDS for Asians in Korea was 10.7% in males and 13.7%, and according to (Fatani et. al. 2015) in the Saudi population young females (ages 29 years or less) had higher levels of EDS than young males (37.7% vs 22.1%). Furthermore, the study showed that females were twice more likely to have EDS compared to young males as they showed to have shorter hours of sleep per night and more hours of sleep during the day.

2.4 TREATMENT OF EDS

2.4.1 Orthodox treatment:

According to (Banerjee et al. 2004), treating the underlying causes of EDS remains the mainstay of therapy but to those who continue to be excessively sleepy, further treatment may be warranted. Traditionally, the amphetamine derivatives which causes the release of noradrenaline from peripheral nerve terminals leading to enhanced sympathetic activity may be applied (which may cause intolerable side effects), methylphenidate and pemoline (collectively sympathomimetics i.e. which mimic the action of the sympathetic nervous system when activated), and psychostimulants were the commonest type of therapy for EDS, particularly in conditions such as narcolepsy.

Most recently the advent of modafinil has broadened the range of therapeutic options. According to Morrison and Riha (2012) the mechanism of modafinil's action is debated, but it is thought to either act as a relatively selective dopamine reuptake inhibitor or via adrenaline, noradrenaline, serotonin or gamma-aminobutyric acid (GABA) systems. Modafinil is commonly used in doses between 200 mg and 400 mg per day, with individualised regimes where doses are given at intervals throughout the day, providing maximum periods of alertness depending on patient requirements (for example, morning, lunchtime and 4 pm, avoiding doses later in the evening where possible to prevent at bedtime) (Morrison and Riha, 2012). Modafinil, a wakefulness promoting drug promotes wakefulness in narcolepsy patients experiencing excessive daytime sleepiness; however, some patients may continue to experience late-day sleepiness. Modafinil has improved executive function in other models of excessive sleepiness. And in a study done by Schwartz (2004) it was proven that for patients with residual late-day sleepiness associated with narcolepsy, an additional 200-mg dose of modafinil taken at midday was effective in sustaining wakefulness throughout the entire waking day. Treatment with modafinil also significantly improved executive function.

Reviews of modafinil safety profile have only identified side-effects classed as “mild to moderate” and include headache, anxiety, nausea and diarrhoea, insomnia and sexual dysfunction, although rare, more severe side-effects have also been described, including fatal skin reactions, hypertension and psychiatric disturbance

(Morrison and Riha, 2012). As a consequence, its use in Europe was restricted to adults and patients without moderate to severe uncontrolled hypertension and cardiac arrhythmias (Morrison and Riha, 2012).

A case report also described a patient who ingested 4500 mg of modafinil in isolation as a suicide attempt and recovered completely within 24 h, suggesting that overdose of this drug alone is unlikely to have a poor outcome. However, another case report described a patient who died following an overdose of modafinil, methylphenidate and hypnotics, which suggests that there is a potential for harm in multiple overdose (Morrison and Riha, 2012).

2.4.2 Other

Caffeine is one of the most commonly ingested alkaloids worldwide. It is present in coffee, tea, soft and energy drinks, chocolate, etc. Currently published data has been stressed that the metyloxantine consumption increases the risk of coronary heart disease, arterial hypertension, arterial stiffness, and an elevation of cholesterol and homocysteine plasma concentration.

The acute high consumption may also modulate insulin sensitivity and glucose blood level. However, the long-term consumption reduces the incidence of the type 2 diabetes mellitus. When administered in high doses the substance may cause various side effects, related to abnormal stimulation of the central nervous system, decrease tonus of the lower esophageal sphincter, as well as increase risk of miscarriage and intrauterine growth retardation.

The final manifestation of side reactions is dependent on the genotype, especially polymorphisms of genes associated with caffeine metabolism, i.e., cytochrome P450CYP1A2 and Catechol-O-methyl transferase (COMT) (Dworzański W, 2009).

According to (Sara M. Seifert et al, 2011) Energy drinks are beverages that contain caffeine, taurine, vitamins, herbal supplements, and sugar or sweeteners and are marketed to improve energy, weight loss, stamina, athletic performance, and concentration. According to self-report surveys, energy drinks are consumed by 30% to 50% of adolescents and young adults.

Frequently containing high and unregulated amounts of caffeine, these drinks have been reported in association with serious adverse effects, especially in adolescents, and young adults with seizures, diabetes, cardiac abnormalities, or mood and behavioural disorders or those who take certain medication and children, especially those with cardiovascular, renal, or liver disease, seizures, diabetes, mood and behavioural disorders, or hyperthyroidism or those who take certain medications, may be at higher risk for adverse events from energy drink consumption s (Sara M. Seifert et al, 2011).

Energy drinks have no therapeutic benefit, and many ingredients are understudied and not regulated. The known and unknown pharmacology of agents included in such drinks, combined with reports of toxicity, raises concern for potentially serious adverse effects in association with energy drink use.

Although healthy people can tolerate caffeine in moderation, heavy caffeine consumption, such as drinking energy drinks, has been associated with serious consequences such as seizures, mania, stroke, and sudden death. (Sara M. Seifert et al, 2011).

Other therapies can include psychostimulants, dexamphetamine, methylphenidate, but in other cases patients may continue to be symptomatic.

2.5 HOMOEOPATHY

2.5.1 Introduction

Homoeopathy, is based on the law of similars and is a system of medical therapeutics that is a natural system of treatment which aims to maintain equilibrium both within the body (homeostasis) and in the entire ecosystem (Chauhan et al., 2007). 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). Homoeopathy differs from allopathy in possessing a precise set of principles governing diagnosis and treatment.

Homoeopathic philosophy is based on the Law of Similars which is a principle of Homoeopathic medicine stating that a drug capable of producing morbid symptoms in a healthy person will cure similar symptoms occurring as a manifestation of disease. An organism under stress typically reacts by producing a unique set of signs and symptoms, these signs and symptoms act like individualistic clues to the homoeopath based on which the indicated corresponding medication is individually selected; the remedy choice is based on the principle of “Similia Similibus Curentur”. This principle dictates that the remedy must have the ability to produce symptoms that are most similar to the disease to be cured in a healthy individual (Chauhan et al., 2007). In homoeopathy, the life force or vital force is a force, power or energy that enlivens the material organism (O’Reilly, 1996); this immaterial being carries out all the functions of life and without this energy the material organism is capable of no sensation, function or self-preservation (Chauhan et al., 2007) it is the ‘vital force’ on which homoeopathic remedies act.

Samuel Hahnemann, a German medical doctor formulated for the first time in the history of medicine the complete laws and principals governing health and disease, and proved them in actual clinical experience (Vithoulkas, 2000). Hahnemann observed from his experiments with Cinchona bark (used as a treatment for Malaria at the time), that the effects he experienced from ingesting the bark were similar to the symptoms of malaria. He therefore reasoned that cure proceeds through similarity, and that treatments must be able to produce symptoms in healthy individuals similar to those of the disease being treated. Through further experiments with other substances, he developed many other homoeopathic remedies, which are widely used today (South African Faculty of Homoeopathy, 2007).

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).

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. 'Proving's', 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.

2.5.2 Use Homoeopathic medicine internationally

According to Singh, Harries and Naidoo (2004) in a study on the prevalence, and pattern of usage of complementary and alternative medicine (CAM), Singh et el (2004) found that the respondents that were using complementary medicine and alternative medicine were also using herbal remedies and spiritual therapies. The results of the study indicated that the use of CAM in South Africa was similar to the findings found in studies done across the world emphasised the need for CAM to be integrated with allopathic medicine (Singh et el, 2004). There are numerous studies that reflect an interest in complementary therapies, with an estimated 45% of the general population in the United State of America using complementary therapies (Pillay, 2013). A study of patients' views conducted the Glasgow Homoeopathic Hospital indicated that patients placed great value on the holistic approach taken by doctors (Mercer and Reilly 2004). In Cuba, health co-operations with the Tuscany Region have been central to the integration of Homoeopathy into the public health system of the country (Rossi et al, 2010). This collaboration and integration has presented a possible solution to the problem that a developing country, such as Cuba, faces in providing sustainable healthcare systems (Rossi et al. 2010).

Marian, Joost, Saini, Von Ammon, Thurneysen and Busato (2008) conducted a study to investigate the patient perception and satisfaction of side effects in homoeopathy compared to conventional care in a primary health care setting, results revealed that there was higher satisfaction in homoeopathic group in a primary care setting and homoeopathic treatment was perceived to be low risk therapy with fewer side effects. A study that was done in India explored the utilization of homoeopathy both in rural and urban areas, the aim of the study was to determine the reasons for patients' preference of homoeopathy; results showed that the reasons for utilization of homoeopathic treatment were due to it having no side effects (Singh, Yadav and Pandey. 2005).

2.5.3 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

According to Vithoulkas (2000) 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 and unless that certain remedy is found, he or she is not cured but at best the condition is only temporarily relieved (Vithoulkas, 2000).

2.5.4 The Law of Similars:

Homoeopathy is a therapeutic method based on the law of similars, thus the name, derived from the Greek word “homoios” meaning similar and “pathos” meaning pain of suffering (Eizayaga, 1991). The law of similars states that a medicine which produces a group of symptoms in a healthy person is able to cure those very symptoms if presented in a diseased person, (Eizayaga, 1991).

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.

2.5.5 The Minimum Dose

Amedeo Avogadro (1776 – 1856) demonstrated that the number of molecules in one mole of any substance is 6.0255 x 1023. Avogadro’s number is of interest to homoeopathy because it specifies the potency (level of deconcentration) at which a remedy does not contain any of the original material substance (Swayne, 2000).

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). According to Shepherd (995) the Arndt’s Law helps to explain the phenomenon of potentization (as discussed in 2.10.8). 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 (higher potency with lower concentration), they should be expected to encourage the healing process. According to (Osawa 2001), the smallest dose will evoke the gentlest, rapid and permanent cure. There is a homoeopathic Law of Cure associated with minute dose levels which 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).

2.5.6 Potentisation

In Homoeopharmaceutics potentisation is a multi-step process (involving dilution and succussion or trituration) by which the inner medicinal power of a crude substance is released (O’Reilly, 1996).

Towsey and Hasan (1995) view potentised homoeopathic medicines, as being biophysical and not biochemical in nature, such medicines probably consist of water crystals imprinted with a 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 (Towsey and Hasan, 1995).

And according to Gaier (1991), pontantisation 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.

The process is theoretically illimitable, though it becomes laboriously time consuming in the higher range of potencies.

2.5.7 Single Remedy Prescription

Homeopathy achieves its best results when single remedies (simplexes) are prescribed one at a time for health problems (Sankaran, R.1991). The principle of Single Remedy Prescription 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. Sometimes, though, it is not always easy to decide which remedy is best. When this happens, a Complex (combination remedy) that combines a number of remedies in the one bottle can be a helpful option. The advantages and limitations of Complexes are explained below (Sankaran, R.1991).

2.5.8 Homoeopathic Complexes

According to Sankaran, R. (1991) the A Complex is a mixture of homeopathic remedies in the one bottle. It may also be called a combination remedy. Complexes can be useful for minor or acute health problems when the needed single remedy is unknown. Complexes are a "quick-fix" when you are unsure of which single homeopathic remedy to use for your problem. They will not interact with other medicines and are safe and simple to use.

Potency is the unit of drug strength. Three scales are used in the preparation of potencies, namely, the decimal scale, centesimal scale and fifty millesimal scale (Chauhan at el., 2007). Hahnemann progressively reduced the dose of a substance by diluting it on a definite scale. This was due to Hahnemann's attempt to reduce the severity of aggravation and this method became known as "potentisation". Crude drugs act on living organisms in three ways, which are mechanical, chemical and dynamic. Potentisation removes the mechanical and chemical aspect but enhances the drug's dynamic properties.

2.5.9 The decimal scale

The decimal scale was introduced by Herring. In this scale, the first potency contains one tenth part of the original drug and each succeeding potency contains one tenth part of the potency preceding it. It is denoted by suffixing the letter 'X' to the number indicating the potency (Chauhan et al., 2007).

2.5.10 The centesimal scale

The centesimal scale was introduced by Hahnemann. In this scale, the first potency contains one hundredth part of the original drug and each succeeding potency contains one hundredth part of the potency preceding it. The potency is denoted by suffixing the letter 'C' (or "CH") to the number indicating the potency (Chauhan et al., 2007).

2.5.11 The fifty millesimal scale

The fifty millesimal scale was introduced by Hahnemann and is based on the instructions given in the 6th edition of his book Organon of Medicine (Chauhan et al, 2007:51). Potentised medicines are prepared using a dilution ratio of 50000 parts of dilutant to 1-part medicinal substance. Also known as LM potencies (O'Reilly, 1996).

The process of potentisation can be carried out by two methods:

2.5.12 Trituration

The main objective of trituration using a pestle and mortar is to reduce the size of the particles of a dry or crude medicinal substance to a finer degree and to homogenously mix them with the vehicle.

2.5.13 Succussion

This is the potentisation process for all soluble substances, be it in water or alcohol (except in a few cases, alcohol is used as a vehicle in most preparations). When water soluble substances attain a 3CH attenuation by trituration, they are converted to alcoholic preparations. The technique used is to take one part of the drug substance and add it to nine parts of the vehicle in a glass vial which is clean, filling it up to 2/3rd of the bottle (Chauhan et al., 2007).

Ten or one hundred downward strokes are given either on the palm of the hand or any soft and firm surface, after carefully corking the bottle. A fresh bottle is utilised each time. This takes the drug-vehicle mixture in the bottle to the first decimal potency level, 1X or 1D. A similar process, with the drug vehicle is used to give the centesimal 1CH potency, i.e. to take one part of the drug substance and add it to ninety-nine parts of the vehicle (Chauhan et al, 2007)

2.5.14 Homoeopathic complexes

According to Kayne (2002), some remedies can be mixed together and administered successfully as a complex despite it being in contradiction to the Hahnemanian principle of prescribing only single remedies. Certain French and German products Traumeel has been extensively researched in over 29 studies and has demonstrated rapid pain relief and anti-inflammatory effects and is considered to be an effective and well-tolerated alternative to NSAIDs (Müller-Löbnitz & Göthel, 2011) (Schnieder, 2011).

Nervoheel N is considered to be a viable alternative to Lorazepam in mild nervous disorders; 248 patients with insomnia, distress, anxiety, restlessness or burnout

(mild nervous disorders) were treated with Nervoheel N or Lorazipam for 4 weeks; significant improvements were noted in both groups according leading to the conclusion that the effect of Nervoheel N was similar to that of Lorazipam (van den Meerschaut & Sünder, 2009).

Neurexan has proven to be an effective, well tolerated alternative to valerian-based combination therapies in treating nervousness/restlessness in a sample of 553 patients in 49 German practices (Hübner, van Haselen & Klein, 2009).

2.6 Composition of experimental homoeopathic complex

The homoeopathic complex applied in the current study comprised the following remedies:

Nux moschata D6

Phosphoricum acidum D30

Helliborus niger D6

Opium D30

The specific homoeopathic remedies chosen for this homoeopathic complex are all well-established; existing remedies used in general clinical practice; each of which is clinically indicated for the signs and symptoms of EDS. It was anticipated that a combination of these well-known homoeopathic remedies based on the respective correlations between their clinical indications and that of the signs and symptoms of EDS (in accordance with the Homoeopathic Law of Similars) would be an effective homoeopathic intervention which broad spectrum sphere of action.

The homoeopathic clinical indications of each remedy (Materia Medica) is as follows:

2.6.1 Nux moschata

Common uses of The remedy:

When the remedy matches the symptoms, Nux moschata has the ability to treat symptoms of allergy, Alzheimer' disease, colic, confusion and forgetfulness, dryness of mouth and constipation, narcolepsy, Petit mal, fainting, and vertigo, all the ailments are accompanied by drowsiness and sleepiness; and inclination to faint (Phatak 2002). This remedy has a tendency of sleepy attacks that are sudden and there is also great sleepiness with all complains (Phatak 2002).

Nux moschata is also indicated typically for conditions associated with drowsiness or dreamy states with vanishing thoughts as well as sleepy attacks accompanied by heaviness of the eyes (Phatak, 2002). Hering (2013:2) states that Nux moschata complaints cause sleepiness, irresistibly drowsy; sleepy muddled, as if intoxicated a strange feeling on waking with great sleepiness, and a great inclination to laughter with restless a sleep.

Complaints cause sleepiness and there is irresistibly drowsiness and there is also muddle as if intoxicated, coma patient lies silently immovable and eyes constantly closed with a strange feeling on waking (Boericke 2008). There is also restless sleep from congestion to heart or head with uterine complaints.

Nux moschata has unconsciousness after mental excitement especially just before menses and thoughts vanish while talking, reading or writing and is listless and indifferent to the point that the patient would go out in the night and not return till searched out and brought back and when awaken there is complete absence of the mind, does not know where he is nor what to answer, sleeplessness (Boericke 2008).

There is senselessness and intoxicated condition, with the absence of the mind and the least exertion or mental excitement brings on somnolency. There is also delirium with violent vertigo and strange gestures with total sleeplessness and stupor and insensibility with unconquerable sleepiness, (Boericke 2008).

2.6.2 Phosphoricum acidum

Phosphoricum acidum is the appropriate homeopathic treatment for depression caused by prolonged suffering or stress, nerve-related hair loss and for mental overexertion in students. This remedy is sleepy by day and is a deep sleeper but when aroused becomes fully conscious (Phatak, 2002). It is also indicated for conditions characterised by debility and nervous exhaustion with mental debility followed by physical debility in those who are overtaxed mentally or physically (Boericke, 2008). When the patient goes from being active and energetic to a state of emotional, physical and mental weakness. He tires easily.

The cause of this general instability is a sustained and silent grievance. We prescribe it for emotional shocks brought upon by traumatic experiences, grief, worries or romantic misfortunes (Boericke, 2008).

Phosphoricum acidum is also for mental over-exertion, for example during exams, contests or other times of stress. The Phosphoricum acidum individual initially suffers from an emotional blockage, which then becomes physical or mental (Boericke, 2008). He is asthenic, indifferent, sad, melancholic, withdrawn and reserved. He is fatigued, exhausted and physically or mentally weakened.

The patient has excessive daytime drowsiness, somnolency and lascivious dreams with emissions. (Boericke, 2008). The common acid "debility" is very marked in this remedy, producing a nervous exhaustion, mental debility first later physical and the mind is Listless with impaired memory, apathetic and indifference. The patient cannot collect his thoughts or find the right word as comprehension is difficult. Effects of grief and mental shock with great stupefaction (Boericke, 2008).

2.6.3 Helleborus niger

This remedy cannot be fully aroused and has sporous sleep (Phatak (2002). It is also indicated for conditions where the brain and mind senses are diminished and responses sluggish, typically indicated for inattentiveness, dullness and apathy and thoughtless staring (Phatak, 2002). The remedy Helleborus niger is widely used for disorders related to the nervous system, including confusion and insipidness and perhaps is also effective in treating conditions wherein the patients seem to show inanity or mental disorders (Boericke, 2008). Helleborus niger has total

unconsciousness, restless and anxious and becomes drowsy when left alone and goes to sleep with constant somnolence and can be aroused but not to full consciousness. Starting with fright in sleep and during sleep muscles twitch and dreams confused, anxious (Boericke, 2008). People who require this medication are usually very slow in answering questions and need tremendous efforts to respond to any query.

Their body has a numb sensation, while the brain does not have any control over the muscles as a result of which objects held by them drops easily from their hand. They are also absentminded and have poor attentiveness commonly accompanied by a condition where the memory becomes completely vacant (Boericke, 2008).

2.6.4 Opium

This remedy is a very good remedy for somnolence (Phatak 2002). It is indicated for states of drowsy stupor, torpidity and sluggishness of function with loss of power and concentration (Phatak, 2002). The effects of Opium are shown in the insensibility of the nervous system the depression, drowsy stupor, painlessness and torpor with general sluggishness and lack of vital reaction, constitute the main indications for the drug.

The mind, patient wants nothing with complete loss of consciousness and an apoplectic state, frightful fancies, the patient is unable to understand or appreciate his sufferings and thinks he is not at home. Delirious talking with wide open eyes (Phatak 2002).

Opium is worse for heat during and after sleep there is carelessness or great anxiety and uneasiness with inconstancy and fickleness. Tranquillity of mind with agreeable reveries and forgetfulness of sufferings with stupidity and imbecility. Loss of consciousness with great flow of ideas, gaiety and a disposition to indulge in sublime and profound reflections there is also vivid imagination and exaltation of the mind, increased courage with stupefaction and dullness (Phatak 2002).

Very easy comprehension illusions of the imagination, mania with fantastical or fixed ideas patient believes contrary to fact that he is not at home. Lethargy with snoring and mouth open eyes open and convulsed and the is face red, and puffed with the jaw hanging and loss of consciousness. There intermittent respiration and

the pulse is slow or even suppressed and convulsive movement of the muscles of face the corners of the mouth, and limbs (Phatak 2002).

Opium has an urgent inclination to sleep, with absolute inability to go to sleep. Incomplete sleep, without power to wake and an uneasy sleep with anxious dreams. Sleeplessness with acuteness of hearing, clocks striking and cocks crowing at a distance keep her awake. Sleeplessness with anxious tossing and restlessness and delirium with a stupefying unrefreshing sleep.

During sleep picking of bedclothes, groaning and moaning (whining) during sleep. There are also terrific shocks in the limbs during sleep. Nightmares and lascivious frightful and anxious dreams and the dreams cannot be roused thus coma vigil (Phatak 2002).

2.7 MEASURING TOOLS

2.7.1 The Epworth sleepiness Scale (ESS)

The apparatus used for the first consultation and the final consultation was the (ESS) (Johns 1991) which was used to determine the level of daytime sleepiness was an inexpensive tool and relatively easy to administer. The client had to self-rate on how likely it is that they would doze in eight different situations. The ESS could be used both as an initial assessment and for ongoing comparative measurements (Johns 1991). ESS is an effective instrument used to measure average daytime sleepiness.

According to (Johns 1997) the ESS has become the world's standard method for making this assessment. Most people can answer the ESS, without assistance in 2 or 3 minutes. The total ESS score provides an estimate of a general characteristic of each person- their average level of sleepiness in daily life. And the ESS has several advantages, not the least of which is the fact that it is very cheap to use and very simple to administer to large numbers of people, it can vary between 0 and 24 in different subjects.

The ESS was applied at the initial consultation and again at the final consultation, the initial measurement served to confirm eligibility for participation i.e. ESS score of 10 or above was required to qualify for the study, this measurement also served

as the baseline measurement against which the final measurement at consultation 3 was compared.

Participants were asked how likely they are to fall asleep (in contrast to just feeling tired):

0= would never doze off

1= slight chance of dozing off

2= moderate change of dozing off

3= high chance of dozing off

In the following situations:

- Sitting and reading
- Watching TV
- Sitting inactive in a public place (e.g. theatre or meeting)
- As a passenger in a car for an hour without a break
- Lying down to rest in the afternoon when circumstances permit
- Sitting and talking to someone
- Sitting quietly after lunch without alcohol
- In a car, while stopped for a few minutes in the traffic

Once completed the scores were totalled and range from 0-24, the higher the score the higher the degree of sleepiness (Bailes, Libman et al. 2006)

An ESS score of greater than or equal to 10 suggested excessive sleepiness (Johns 1991) (Morrison and Riha 2012) (Hayley, Williams et al. 2014) originating from inadequate sleep hygiene and insufficient sleep syndrome (Banerjee, Vitiello et al. 2004) (Hayley, Williams et al. 2014).

2.7.2 The Stanford Sleepiness Scale (SSS)

The other apparatus used that was used during the consultations was The SSS; a self-rating scale is the most broadly used and time efficient subjective sleepiness measuring instrument, administered at 2 hour intervals during the day (Shahid, 2010). It consists of a 7-point scale of equal intervals starting from 1 (being very alert) to 7 (being excessive sleepy) (Herscovitch & Broughton 1981).

The SSS was completed on a daily basis by each participant; for one week prior to commencing treatment the participant will complete the SSS, followed by an additional two weeks of daily completion of the SSS (on treatment). Participants rated their degree of sleepiness on an hourly basis throughout the awake period of the day using a seven point Guttman scale (Bailes, Libman et al. 2006) in the following manner:

1 = Feeling active, vital, alert, or wide awake

2= Functioning at high levels, but not peak; able to concentrate

3= Awake, but relaxed; responsive but not fully alert

4= somewhat foggy, let down

5= Foggy; losing interest in remaining awake; slowed down

6= Sleepy, woozy, fighting sleep; prefer to lie down

7= No longer fighting sleep, sleep onset soon; having dream-like thoughts

X= Asleep

Participants choose the option which most suitably describes how they were feeling at the time of testing (Bailes, Libman et al. 2006). Scoring 3 or more during periods when one should be alert is suggestive of one experiencing sleep debt and more sleep is required.

2.8 VALIDITY AND RELIABILITY STATISTICS

According to Smyth (2012) the Epworth Sleepiness Scale has a high level of internal consistency between the 8 items as measured by Cronbach's alpha, ranging from 0.74 to 0.88. Numerous studies using the ESS have supported high validity and reliability.

The Stanford Sleepiness Scale (SSS) (Hoddes et al. 1973) measures how alert a person is during the course of the day. It ranges from 1 to 7, 1 being very alert and 7 being excessively sleepy. If a person is rating 3 and below then the person should be feeling alert. This tool is currently used widely in many studies of sleep disorders and effects of sleep deprivation. The SSS is sufficiently sensitive to reveal sleepiness induced by sleep deprivation, however, it is not so sensitive with patients suffering with sleep disorders and tending to deny sleepiness (Shahid et al. 2010).

CHAPTER THREE

MATERIALS AND METHODS

3.1 RECRUITMENT

Recruitment was through advertising in a form of a research poster & Flyers (approved by the Faculty of Health Sciences RHDC and the DUT IREC) it was displayed and disseminated on the DUT campuses (see Appendix A), and some of the recruitments were done by word of mouth. Those who respond to the respective advertisements and flyers and word of mouth contacted the researcher directly and they were intern booked for their respective appointments at the DUT Homoeopathic Day Clinic.

3.2 SAMPLING

Since no sample frame was available on this population, non-probability sampling in the form of convenience sampling was applied whereby the first 30 (N=30) consenting respondents who met the inclusion and exclusion criteria of the study were recruited.

The study followed a randomised, double blind, placebo controlled pre-test post-test design. By means of convenience sampling out of the 30 suitable participants that were recruited were randomly allocated to two groups (20 treatment receiving the above mentioned homoeopathic complex and 10 a placebo). Respondents who agreed to participate in the program were given an information form (see Appendix B), and the respondents were assessed according to the selection criteria and required to answer The Epworth Sleepiness Scale (see Appendix D). Those who were fit the parameters were required to sign an informed consent form (see at the end of Appendix B).

3.3 RANDOMISATION

A randomisation list was prepared by an independent clinician within the Department of Homoeopathy at DUT – Dr M. Maharaj. Thirty pieces of paper each uniquely numbered from 1-30 were placed in a container, ten unique pieces of paper were drawn from the hat (each piece were replaced into the hat after being drawn) the first 10 numbers drawn comprised the placebo group (n=10) and the remaining 20 the active treatment group (n=20) once this process was complete a randomisation list was compiled accordingly. The randomisation list remained blind to the researcher, research supervisor and the participants and it was held securely by the independent clinician until the research was un-blinded – this ensured a double-blind methodology. The dispensing of the respective medicine i.e. placebo or active treatment was governed by the randomisation list allocation of each participant.

3.4 SELECTION OF TEST RESPONDENTS

Selection of test respondents was according to The Epworth Sleepiness Scale (ESS) (Johns, 1991) where they were a result of a high chance of dozing, in contrast to feeling just tired.

3.4.1 Inclusion criteria

Participants must have:

- Been between 18 and 30 years of age Been a registered tertiary education student
- Been willing to follow the respective research process including 3 consultations with the researcher as well as comply with the research protocol and provide written informed consent
- Been in a general good state of health
- Had a ESS score of greater or equal to 10 [which suggests excessive sleepiness] (Johns 1991) (Morrison and Riha 2012) (Hayley, Williams et al. 2014) originating from inadequate sleep hygiene and insufficient sleep syndrome (Banerjee, Vitiello et al. 2004) (Hayley, Williams et al. 2014).

3.4.2 Exclusion criteria

Participants were not considered for inclusion if:

- They were younger than 18 or older than 30
- They were currently taking chronic or acute medication (orthodox, homoeopathic, herbal or other) for any medical condition
- They made use of any recreational drugs and drugs of abuse
- They suffered or had any history of narcolepsy, obstructive sleep disorder (apnoea), mood disorders or circadian rhythm disorders
- They were suffering from any chronic or debilitating disease
- They were night shift workers or had travelled internationally within the last 6 weeks before the research began.
- They were commercial/occupational drivers, machine operators or pilots or had a history of sleep-associated incidents (Pagel 2009)

3.5 ETHICS

This study met the requirements that were laid out in the Declaration of Helsinki (WMA 2008) as well as complied with the South African Department of Health Ethics in Health Research guidelines (DOH 2004). In addition to that stipulated within the Ethics Checklist the following were specifically implemented:

- Voluntary participation free from coercion or undue incentives
- Participants were free to withdraw from the study at any stage without the need for providing a reason for their withdrawal
- Confidentiality was maintained i.e. all participant's records were stored securely within a secure research storage facility within the Department of Homoeopathy, and ultimately shredded after 5 years. When data was disseminated participants were referred to by unique participant numbers and their respective identities were disclosed.
- Written informed consent was obtained from all participants prior to commencing the research project.
- All risks participation had been carefully considered and based on the consideration the study was determined to be of 'minimal risk'

- Ethical clearance was granted by the DUT Institutional Research Ethics Committee (IREC) clearance number REC REC 75/16 – See appendix M.

3.6 MEASURING TOOLS

3.6.1 The Epworth Sleepiness Scale

Patients that had an ESS score of greater or equal to 10 [which suggests excessive sleepiness] originating from inadequate sleep hygiene and insufficient sleep syndrome (Banerjee, Vitiello et al. 2004) were the ones included in the study (Hayley, Williams et al. 2014). The ESS tool helped to identify successfully the individuals that were suffering from excessive sleepiness.

3.6.2 The Stanford Sleepiness Scale

When the patients qualified for the study, the other apparatus that was used during the consultations was the SSS which was a self-rating scale (Shahid, 2010). The SSS was completed on a daily basis by each participant; for one week prior to commencing treatment the participant will complete the SSS, followed by an additional two weeks of daily completion of the SSS (on treatment) (Bailes, Libman et al. 2006).

3.7 CONSULTATIONS

3.7.1 Initial consultation

The following took place at the first consultation:

- Informed consent process and signing of main informed consent form
- Confirmation of diagnosis
- Confirmation that criteria for inclusion was met (Including ESS >10)
- Physical examination and case history (See appendix E and F)
- Explanation of research procedure

- Explanation of how to complete the Stanford Sleepiness Scale

3.7.2 Second consultation (after a minimum of 7 days after the first consultation)

The following took place at the second consultation:

- Handing in of 7 days' baseline SSS by the patient – verification by researcher for correctness
- Completion of the baseline ESS (at the consultation)
- Dispensing of the experimental medication (placebo or active)
- Explanation of dosage and posology of medication
- Issuing of two further 7 day SSS log sheets

3.7.3 Third consultation (after a minimum of 14 days after the second consultation)

The following took place at the third consultation:

- Handing in of 7 days' baseline SSS by the patient
- Completion of the final ESS (at the consultation)
- Retrieving of empty medicine containers
- Physical examination and case history
- Referral of participant for further care if necessary
- Participants had to return their remedy bottles at the close out consultation which allowed the researcher to assess compliance.

3.8 TREATMENT

3.8.1 Remedy manufacture

The experimental medicine was in the form of a homoeopathic complex comprising the following pre-existing homoeopathic remedies (the specific combination of ingredients is unique for this research):

Nux moschata D6

Phosphoricum acidum D30

Helliborus niger D6

Opium D30

The homoeopathic complex was prepared according to the methods described in the German Homoeopathic Pharmacopoeia (Driehsen 2003). The medication in accordance with homoeopharmaceutical methods was prepared in 20% ethanol solution. See appendix R.

Since there were two additional concurrently run trials on EDS (one applying a herbal liquid complex and one a simillimum study in liquid format) a liquid complex was chosen so that all three experimental interventions were standardized in liquid format for this study.

The placebo intervention comprised 50ml of 20% ethanol and distilled water solution, which was indistinguishable in appearance and taste to that of the homoeopathic complex.

Alcohol:

- Sigma-Aldrich ethanol puriss p.a
- Expiry date: 12/2019
- Lot#SZBF1900V

Water:

- Purite water purification system select fusion, reverse osmosis.

3.8.2 Dosage and posology

Each participant was provided with 50ml of the homoeopathic complex (or placebo) in a 50ml amber glass dropper bottle and the dosage will be 10 drops placed directly under the tongue three times daily i.e. in the morning on waking, at midday and in the evening.

3.8.3 Rationale for the homoeopathic complex

Individual ingredients within the complex were chosen based on a EDS symptomatic reportorial extraction using Radar Version 10 (see Appendixes O,P,Q) and a review of related remedies – the final selection of remedies was based on the materia medica of remedies which corresponded clinically to the typical symptoms of EDS was reviewed and a final selection was made based on a group of remedies which collective materia medica most comprehensively corresponded with the symptoms of EDS commonly this is commonly referred to as 'homoeopathic polypharmacy' (Gaier 1991) or 'Complex remedies' (Kayne 2006) and the potencies of respective ingredients in such complexes usually range from Ɵ – 30CH (Gaier 1991).

CHAPTER FOUR

THE RESULTS

4.1 INTRODUCTION

This chapter presents the results of the data derived from the two measurement tools applied namely the Epworth Sleepiness Scale (ESS) and the Stanford Sleepiness Scale, it also presents the demographics of the research sample. The data obtained from the two measurement tools was analysed with SPSS version 24.0. The results will present the descriptive statistics in the form of graphs, cross tabulations and other figures for the quantitative data that was collected. Inferential statistical techniques included the use of correlations and chi square tests values; which are interpreted using the p-values generated.

4.2 THE SAMPLE

The research sample comprised 35 participants (n=35) which were divided into two groups; a treatment group (n=23) and a placebo group (n=12). The sample was selected by convenience according the method and criterion listed in sections 3.1 – 3.4.

4.3 BIOGRAPHICAL DATA OF RESPONDENTS

This section summarises the biographical characteristics of the participants. Participant demographics are described in terms of the following demographic characteristics: gender (Figure 4.1) and age (Table 4.2and Table 4.3). As shown in Table 4.1, the complex group had proportionally more males whilst this trend was reversed for females. Moreover, and as shown in Table 4.2, there was not much difference in the age distribution characteristics.

Table 4.1 Gender distribution Table 2.

			Group		Total
			Complex	Placebo	
Gender:	Male	Count	11	4	15
		% within Group	47.8%	33.3%	42.9%
	Female	Count	12	8	20
		% within Group	52.2%	66.7%	57.1%
Total		Count	23	12	35
		% within Group	100.0 %	100.0 %	100.0 %

Table 4.2 The descriptive statistics for age

Group	N	Mean	Std. Deviation	Minimum	Maximum	Range
Complex	23	22.2174	1.85758	20.00	28.00	8.00
Placebo	12	22.8333	2.20880	20.00	26.00	6.00
Total	35	22.4286	1.97463	20.00	28.00	8.00

Table 4.3 Gender by Age by Group

Group	Gender	N	Mean	Std. Deviation	Minimum	Maximum	Range
Complex	Male	11	22.2727	2.28433	20.00	28.00	8.00
	Female	12	22.1667	1.46680	20.00	25.00	5.00
	Total	23	22.2174	1.85758	20.00	28.00	8.00
Placebo	Male	4	24.5000	1.73205	22.00	26.00	4.00
	Female	8	22.0000	2.00000	20.00	26.00	6.00
	Total	12	22.8333	2.20880	20.00	26.00	6.00
Total	Male	15	22.8667	2.32584	20.00	28.00	8.00
	Female	20	22.1000	1.65116	20.00	26.00	6.00
	Total	35	22.4286	1.97463	20.00	28.00	8.00

4.4 THE EPWORTH SLEEPINESS SCALE

The research instrument consisted of 8 items, with a level of measurement at an ordinal level. The instrument was applied at three intervals (3 measurements); initially at recruitment stage, pre-intervention (measurement 2) and post-intervention (measurement 3).

4.4.1. Reliability of the ESS

Reliability is computed by taking several measurements on the same subjects. A reliability coefficient of 0.70 or higher is considered as “acceptable”. The table below reflects the Cronbach’s alpha score for all the items that constituted the questionnaire. As shown in Table 4.4, each group on its own showed larger variations in the scoring patterns which resulted in lower than normal Cronbach alpha scores. In contrast, the reliability scores for the combined group however, exceed the recommended Cronbach’s alpha value (*). This indicates a degree of acceptable, consistent scoring for these sections of the research.

Table 4.4 Survey scales and Predictor variables in Quantitative Analysis

Survey scales	Predictor variables	**Number of Items**	**Cronbach's Alpha score**
1	Complex	8	0.497
2	Placebo	8	0.462
3	Combined	8	0.798*

4.4.2 ESS Factor Analysis

This section reports on the variables obtained from the ESS. In general, and as derived from the rotated varimax with Kaiser normalisation, the scale elicited respondent's perceptions of their degree of sleepiness. Eight critical question were used in assessing the respondent's degree of sleepiness, namely: sitting and reading; watching TV; sitting inactive in a public place; as a passenger in a car for an hour without a break; lying down to rest in the afternoon when circumstances permit; sitting and talking to someone; sitting quietly after lunch without alcohol; and in car, while slopped for a few minutes in traffic.

Before the interpretation of the findings from the factor analysis, it is worth mentioning that as a general requirement, Kaiser-Meyer-Olkin measurement of sampling adequacy should be greater than 0.50 and Bartlett's test of Sphericity less than 0.05 for factor analysis procedure. The matrix tables highlighted in Table 4.5 reflects the results of Kaiser-Meyer-Olkin measure of sampling adequacy as well as the Bartlett's Test of Sphericity for both Complex, Placebo, and Combined. As shown in Table 4.5, the average loading of items by components was above the acceptable Kaiser-Meye values (> 0.50) and Bartlett's values (< 0.05) for all the themes, which according to Schwarz (2011: 26), indicated that the data of the current study may be analysed by means of factor analysis.

Factor analysis is a statistical technique whose main goal is data reduction. A typical use of factor analysis is in survey research, where a researcher wishes to represent a number of questions with a small number of hypothetical factors.

- The principle component analysis was used as the extraction method, and the rotation method was Varimax with Kaiser Normalization. This is an orthogonal rotation method that minimizes the number of variables that have high loadings on each factor. It simplifies the interpretation of the factors.
- Factor analysis/loading show inter-correlations between variables.
- Items of questions that loaded similarly imply measurement along a similar factor. An examination of the content of items loading at or above 0.5 (and using the higher or highest loading in instances where items cross-loaded

at greater than this value) effectively measured along the various components.

Table 4.5 ESS KMO and Bartlett's Test

		Complex	Placebo	Combined
Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		.600	.536	.718*
Bartlett's Test of Sphericity	Approx. Chi-Square	46.878	44.720	93.442
	Df	28	28	28
	Sig.	.014	.024	.000*

4.4.2.1 ESS Factor Analysis Homoeopathic Complex Group

It is noted that the variables that constituted this section loaded along 3 components (sub-themes). This means that respondents identified different trends within the section. Within the section, the splits are colour coded. Notably, the coloured coded value indicated that the factors constituted the various sections (themes) loaded perfectly along the component in each instance.

Moreover, the un-coded value revealed that there is variation across the various sections (themes) along the 3 component in each instance. This implies that there is inconsistency with the scoring patterns of the respondents measured (Table 4.6).

Table 4.6 Homoeopathic Complex Group Rotated Component Matrix[a]

	Component		
	1	2	3
Sitting and reading	.064	.155	.831
Watching TV	.627	.268	.011
Sitting inactive in a public place (e.g. a theatre or a meeting)	.320	.642	-.052
As a passenger in a car for an hour without a break	.607	-.214	.309
Lying down to rest in the afternoon when circumstances permit	-.049	.765	.132
Sitting and talking to someone	.660	-.309	-.312
Sitting quietly after a lunch without alcohol	.300	.576	-.499
In a car, while stopped for a few minutes in traffic	.898	-.184	-.053

Extraction Method: Principal Component Analysis.

Rotation Method: Varimax with Kaiser Normalization.

a. Rotation converged in 5 iterations.

4.4.2.2 ESS Factor Analysis Placebo Group

It is noted that the variables that constituted this section loaded along 3 components (sub-themes). This means that respondents identified different trends within the section. Within the section, the splits are colour coded. The coloured coded value indicated that the factors constituted the various sections (themes) loaded perfectly along the component in each instance. This implies that the statements that constituted the sections measured what is set out to measure.

Moreover, the un-coded value revealed that there is variation across the various sections (themes) along the 3 component in each instance. This implies that there is inconsistent with the scoring patterns of the respondents measured (Table 4.7).

4.4.2.3 ESS Factor Analysis Combined Group

It is also noted that the variables that constituted this section loaded along 2 components (sub-themes). This means that respondents identified different trends within the section. Within the section, the splits are colour coded. Notably, the coloured coded value indicated that the factors constituted the various sections (themes) loaded perfectly along the component in each instance (Table 4.8).

Moreover, the un-coded value revealed that there is variation across the various sections (themes) along the 2 component in each instance. This implies that there is inconsistent with the scoring patterns of the respondents measured.

Table 4.7 Placebo Group Rotated Component Matrix[a]

	Component		
	1	2	3
Sitting and reading	.201	-.258	.646
Watching TV	.713	-.262	-.089
Sitting inactive in a public place (e.g. a theatre or a meeting)	.169	.594	.083
As a passenger in a car for an hour without a break	.690	.282	-.003
Lying down to rest in the afternoon when circumstances permit	.185	.750	.263
Sitting and talking to someone	.270	.731	.133
Sitting quietly after a lunch without alcohol	.146	-.219	.819
In a car, while stopped for a few minutes in traffic	.845	.339	.072

Extraction Method: Principal Component Analysis.

Rotation Method: Varimax with Kaiser Normalization.

a. Rotation converged in 6 iterations.

Table 4.8: Combined Group Rotated Component Matrix[a]

	Component 1	2
Sitting and reading	.740	.310
Watching TV	.476	.376
Sitting inactive in a public place (e.g. a theatre or a meeting)	.304	.783
As a passenger in a car for an hour without a break	-.038	.819
Lying down to rest in the afternoon when circumstances permit	.723	-.012
Sitting and talking to someone	.744	.324
Sitting quietly after a lunch without alcohol	.705	.031
In a car, while stopped for a few minutes in traffic	.224	.857

Extraction Method: Principal Component Analysis.

Rotation Method: Varimax with Kaiser Normalization.

a. Rotation converged in 3 iterations.

4.5 ANALYSIS OF ESS DATA – SECTION ANALYSIS

The section that follows analyses the scoring patterns of the participants per variable per section. The results are first presented using summarised percentages for the variables that constitute each section. Results are then further analysed according to the importance of the statements. The traditional approach to reporting a result requires a statement of statistical significance. A **p-value** is generated from a **test statistic.** A significant result is indicated with "p < 0.05". Each question within ESS was numbered from 1-8 and analysed individually and compared between groups at the three intervals of measurement.

Table 4.9 The table below indicates the relationship between the two groups by individual reading.

		Never	Slight	Moderate	High	Fisher's Exact Test
ESS_1_1	Complex	8.7	26.1	39.1	26.1	0.261
	Placebo	9.1	0.0	45.5	45.5	
ESS_1_2	Complex	8.7	21.7	39.1	30.4	0.546
	Placebo	18.2	36.4	18.2	27.3	
ESS_1_3	Complex	0.0	13.0	39.1	47.8	0.626
	Placebo	9.1	9.1	45.5	36.4	
ESS_1_4	Complex	4.3	21.7	17.4	56.5	0.748
	Placebo	9.1	9.1	27.3	54.5	
ESS_1_5	Complex	0.0	8.7	26.1	65.2	1.000
	Placebo	0.0	0.0	27.3	72.7	
ESS_1_6	Complex	39.1	43.5	17.4	0.0	0.150
	Placebo	72.7	27.3	0.0	0.0	
ESS_1_7	Complex	4.3	8.7	8.7	78.3	0.086
	Placebo	0.0	0.0	45.5	54.5	
ESS_1_8	Complex	13.0	34.8	21.7	30.4	0.429
	Placebo	27.3	27.3	36.4	9.1	
ESS_2_1	Complex	8.7	21.7	39.1	30.4	0.416
	Placebo	9.1	0.0	45.5	45.5	
ESS_2_2	Complex	8.7	21.7	39.1	30.4	0.546
	Placebo	18.2	36.4	18.2	27.3	
ESS_2_3	Complex	0.0	17.4	39.1	43.5	0.608
	Placebo	9.1	9.1	45.5	36.4	
ESS_2_4	Complex	4.3	17.4	21.7	56.5	1.000
	Placebo	9.1	9.1	27.3	54.5	
ESS_2_5	Complex	0.0	8.7	30.4	60.9	0.385
	Placebo	9.1	0.0	18.2	72.7	
ESS_2_6	Complex	39.1	43.5	17.4	0.0	0.531
	Placebo	63.6	27.3	9.1	0.0	
ESS_2_7	Complex	4.3	13.0	8.7	73.9	0.068
	Placebo	0.0	0.0	45.5	54.5	

ESS_2_8	Complex	13.0	34.8	26.1	26.1	0.549
	Placebo	27.3	27.3	36.4	9.1	
ESS_3_1	Complex	52.2	26.1	8.7	13.0	0.531
	Placebo	54.5	45.5	0.0	0.0	
ESS_3_2	Complex	52.2	17.4	26.1	4.3	0.743
	Placebo	45.5	36.4	18.2	0.0	
ESS_3_3	Complex	60.9	26.1	8.7	4.3	1.000
	Placebo	63.6	27.3	9.1	0.0	
ESS_3_4	Complex	56.5	8.7	21.7	13.0	0.213
	Placebo	27.3	36.4	18.2	18.2	
ESS_3_5	Complex	4.3	52.2	13.0	30.4	0.020
	Placebo	27.3	36.4	36.4	0.0	
ESS_3_6	Complex	73.9	8.7	17.4	0.0	0.207
	Placebo	72.7	27.3	0.0	0.0	
ESS_3_7	Complex	21.7	21.7	30.4	26.1	0.225
	Placebo	45.5	27.3	27.3	0.0	
ESS_3_8	Complex	69.6	13.0	13.0	4.3	0.019
	Placebo	27.3	63.6	9.1	0.0	

The fisher's exact tests individual readings for the degree of sleepiness is summarised in Table 4.9 above. As indicated by the level of significance, it was noted that there was no statistically significant difference between the complex and the placebo in the majority of the individual readings($p>0.05$).

On the other hand, it was observed that there was a significant difference in the scoring pattern between the complex and placebo with respect to ESS_3_5 (lying down to rest in the afternoon when circumstances permit) and ESS_3_8 (in a car while stopped in traffic for a few minutes) individual reading, respectively ($p< 0.05$) these differences were found to exist between comparisons made at the third and final measurement. To be specific, and with regard to the ESS_3_5the majority of the respondents (52.2%) in the homoeopathic complex group indicated that there was only a 'slight' chance of dozing off in this setting, whereas those in the placebo

group indicated that they had slight (36.4%) and moderate (36.4%) chance of dosing off in this setting (lying down to rest in the afternoon when circumstances permit).

Regarding the ESS_3_8, 69.6% of those in the homoeopathic complex group stated that the was no chance of dozing off in this setting and only 13% sated that there was a slight chance of dosing off in this setting; in contrast more than 63% of those in the placebo group stated there was slight chance of dosing off in a car, while stopped for a few minutes in traffic and only 27% stated that there was no chance of dosing off in this setting.

Overall, it can be inferred that at the conclusion of the study with respect to variables 5 & 8 those in the homoeopathic Complex group were less sleepy than those in the placebo group.

4.5.1 ESS comparison of means

To determine whether parametric tests could be used, a One-Sample KolmogorovSmirnov Test was done. The normal distribution of the degree of sleepiness is presented in Table 4.6. The One-Sample Kolmogorov-Smirnov test for the normality revealed no significant differences against the normality of the variables ($p > 0.05$). Hence it can be inferred that the distributions are normal and that the t-test and ANOVA can be used to analyse the respective data set.

Table 4.10 Normal Distribution Test

		ESS - Total 1	ESS - Total 2	ESS - Total 3
N		34	34	34
Normal Parameters[a,b]	Mean	15.6471	15.3824	6.9412
	Std. Deviation	3.40127	3.50769	4.76058
Most Extreme Differences	Absolute	.155	.148	.147
	Positive	.105	.104	.147
	Negative	-.155	-.148	-.106
Test Statistic		.155	.148	.147
Asymp. Sig.	.058[c]	.056[c]	.059[c]	

a. Test distribution is Normal.

b. Calculated from data.

c. c. Lilliefors Significance Correction.

4.5.2 ESS Intra-Group analysis

The intra-group relationship of the participant's individual scores within the homoeopathic complex and placebo groups is explained in this section.

4.5.2.1 ESS Intra-group analysis of Placebo group

With regards to the Placebo group and as indicated by the level of significance in Table 4.11, it can be observed that there was a strong correlation between ESS-Total scores 1 (at recruitment) and ESS-Total score 3 (at close out) (r = 0.817) with respect to the pair 1 reading. Similar positive correlation was also observed in pair

3, which shows a strong correlation between ESS-Total score 2 (baseline) and ESS-Total score 3 (at close out) (r = 0.817).

An examination of the means for ESS - Total 1 - ESS - Total 3 (for example) indicates that the first reading values (14.9) are significantly higher than the 3rd readings (6.00).

A similar pattern is observed for 2nd and 3rd readings (14.9 & 6.0 respectively). This can be further supported by the t-test analysis in Table 4.12, as there were statistically significant differences for the pair 2 and pair 3.

It is worth noting that the correlation coefficient for pair 1 could not be computed. This was attributed to the standard error differences between ESS-Total 1 and ESS-Total 2 being zero.

Table 4.11: Mean, standard deviation, and correlation for Placebo sample

		Mean	N	Std. Deviation	Std. Error Mean	Correlation	*P*-Value
Pair 1	ESS - Total 1	14.9091[a]	11	3.64567	1.09921		
	ESS - Total 2	14.9091[a]	11	3.64567	1.09921		
Pair 2	ESS - Total 1	14.9091	11	3.64567	1.09921	0.817*	0.002*
	ESS - Total 3	6.0000	11	3.49285	1.05313		
Pair 3	ESS - Total 2	14.9091	11	3.64567	1.09921	0.817*	0.002*
	ESS - Total 3	6.0000	11	3.49285	1.05313		

a. The correlation and t cannot be computed because the standard error of the difference is 0.

Table 4.12 Independent Paired Samples Test for Placebo

	Paired Differences					t	df	Sig. (2tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Pair 2 ESS - Total 1 - ESS - Total 3	8.90909	2.16585	.65303	7.45405	10.36413	13.643	10	.000*
Pair 3 ESS - Total 2 - ESS - Total 3	8.90909	2.16585	.65303	7.45405	10.36413	13.643	10	.000*

In summary one can state that within the placebo group total ESS scores differed significantly when comparing them at recruitment (ESS Total 1) and at close out (ESS Total 3) i.e. mean total scores were significantly lower at close out and participants were thus significantly less sleepy. The same was noted when comparing them at baseline (ESS Total 2) and at close out (ESS Total 3) – participants were thus less sleepy at the end of the study within this group.

4.5.2.2 ESS Intra-group analysis of Homoeopathic Complex group

With regard to the homoeopathic complex readings in Table 4.13, a positive strong correlation was observed with respect to pair 1, that is ESS-Total scores 1 (at recruitment) and ESS-Total scores 2 (at baseline) reading (r = 0.920). There was however little correlation for the pair 2 (r =0.313) and pair 3 (r = 0.223) individual reading.

Table 4.13 Mean, standard deviation, and correlation for Complex sample

		Mean	N	Std. Deviation	Std. Error Mean	Correlation	Sig.
Pair 1	ESS - Total 1	16.0000	23	3.30289	.68870	0.920*	0.000*
	ESS - Total 2	15.6087	23	3.49986	.72977		
Pair 2	ESS - Total 1	16.0000	23	3.30289	.68870	0.313	0.146
	ESS - Total 3	7.3913	23	5.27205	1.09930		
Pair 3	ESS - Total 2	15.6087	23	3.49986	.72977	0.223	0.306
	ESS - Total 3	7.3913	23	5.27205	1.09930		

In contrast to the correlation result, the reverse was the case for the t-test analysis for the Homoeopathic Complex Group. From Table 4.14, it was gathered that ESS-Total 1 and ESS-Total 2 had no significant differences for the pair 1 ($p>0.05$) this is to be expected since both of these scores were pre-treatment scores (at recruitment and at baseline respectively), whereas a statistical difference was observed for the

pair 2 and pair 3 ($p<0.05$) i.e. between recruitment scores and close out scores (pre and post treatment) and between baseline scores and close out scores (pre and post treatment). A close examination of the means for the Homoeopathic Complex Group indicates that pair 3 had the highest mean (8.6 ± 5.6) when compared against pair 1 (0.39 ± 1.3).

Table 4.14 Independent Paired Samples Test for Homoeopathic Complex

	Paired Differences						Df	Sig. (2tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Pair 1 ESS - Total 1 - ESS - Total 2	.39130	1.37309	.28631	-.20246	.98507	1.367	22	.186
Pair 2 ESS - Total 1 - ESS - Total 3	8.60870	5.27205	1.09930	6.32889	10.88850	7.831	22	.000*
Pair 3 ESS - Total 2 - ESS - Total 3	8.21739	5.64041	1.17611	5.77829	10.65649	6.987	22	.000*

One can summarise then that there was a statistically significant improvement in ESS scores (a lowering in total ESS score) in participants who received the Homoeopathic Complex suggesting that they were significantly less sleepy by the end of the study.

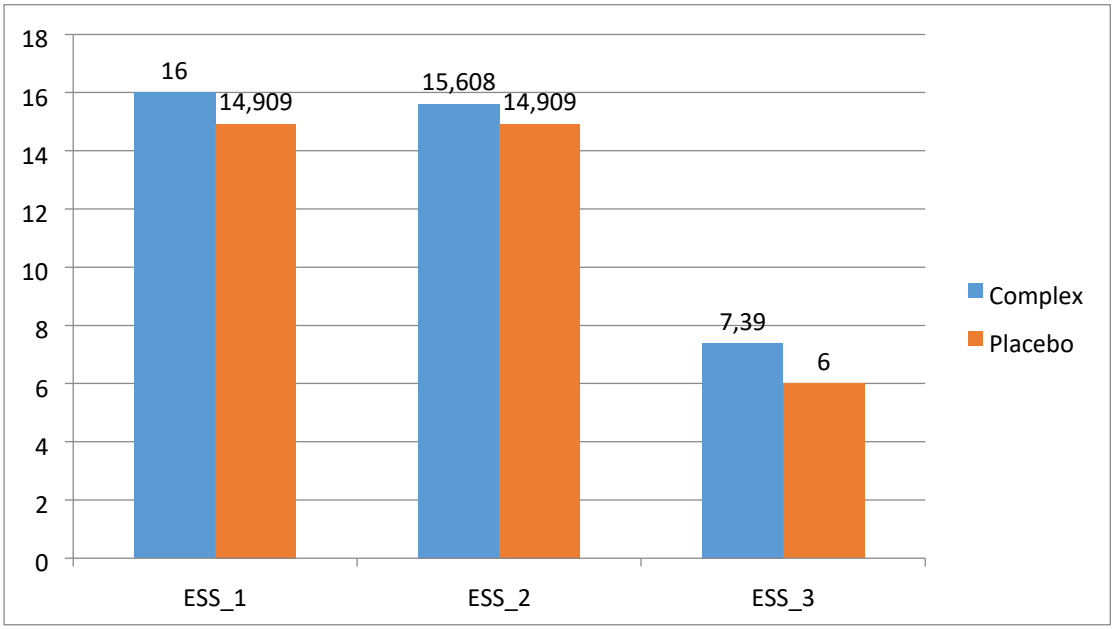

Figure 4.1 Comparison of ESS means per group

As seen in Figure 4.1 when comparing mean total scores of the ESS data one can clearly observe that the respective scores were significantly lower at close out (ESS_3) in both groups.

4.5.3 ESS Inter-Group Analysis

The inter-group relationship of the participant's individual readings for both the Placebo and Homoeopathic Complex is explained in this section.

From Table 4.15, it can be gathered that the highest mean for the Homoeopathic Complex Group was recorded for ESS-Total 1 (16±3.3) (at recruitment), whereas the ESS-Total 3 (at close out) recorded had the lowest ESS reading (7.4±5.3).

In terms of the Placebo reading, similar trends could also be observed. For example, the ESS-Total 3 recorded the lowest mean value (6± 3.5) (at close out), while ESS

Total 1 and ESS-Total 2 had similar mean value (14.9±3.6) (at recruitment and baseline respectively).

Overall, the ANOVA result presented in Table 4.16 showed that both the Homoeopathic Complex and exhibited no statistical differences ($p>0.05$) between each other at the three levels of measurement (Recruitment ESS_1; Baseline ESS_2 & Close out ESS_3). This implies that the means were not statistically different from one another.

In Figure 4.2total ESS scores were categorised into three groups relating to the level of sleepiness; 0-6 (slight) 7-8 (moderate) 9-24 (severe/very sleepy) and compares the differences in the respondents scoring pattern regarding the degree of sleepiness. As gleaned from the figure below, it can be observed that at recruitment stage (ESS-Total
1) and baseline (ESS-Total 2), 100% of participants (both groups) were classified as 'severe/very sleepy' (total score ESS score >9)

Moreover, and with respect to the ESS-Total 3 (at close out), there were differences in the participants scoring pattern with regards to the Complex and Placebo groups. For example, at close out 52.2% of those in the Homoeopathic Complex group had a total ESS score of 6 or less (slightly sleepy) compared with those in the Placebo group only 45% of which achieved total ESS scores of 6 or less. More so, it was observed that 17.4% of those in the Homeopathic Complex group obtained total scores of 7-8 (moderately sleepy) while 36.4% in the Placebo group were such.

Table 4.15: Mean, Standard deviation, minimum, and range for both Complex and Placebo

Group		ESS - Total 1	ESS - Total 2	ESS - Total 3
Complex	N	23	23	23
	Mean	16.0000	15.6087	7.3913
	Std. Deviation	3.30289	3.49986	5.27205
	Minimum	10.00	10.00	2.00
	Maximum	23.00	23.00	23.00
	Range	13.00	13.00	21.00
Placebo	N	11	11	11
	Mean	14.9091	14.9091	6.0000
	Std. Deviation	3.64567	3.64567	3.49285
	Minimum	10.00	10.00	1.00
	Maximum	20.00	20.00	11.00
	Range	10.00	10.00	10.00
Total	N	34	34	34
	Mean	15.6471	15.3824	6.9412
	Std. Deviation	3.40127	3.50769	4.76058
	Minimum	10.00	10.00	1.00
	Maximum	23.00	23.00	23.00
	Range	13.00	13.00	22.00

Table 4.16: ANOVA Table

			Sum of Squares	df	Mean Square	F	Sig.
ESS - Total 1 * Group	Between Groups	(Combined)	8.856	1	8.856	.760	.390
	Within Groups		372.909	32	11.653		
	Total		381.765	33			
ESS - Total 2 * Group	Between Groups	(Combined)	3.642	1	3.642	.290	.594
	Within Groups		402.387	32	12.575		
	Total		406.029	33			
ESS - Total 3 * Group	Between Groups	(Combined)	14.404	1	14.404	.628	.434
	Within Groups		733.478	32	22.921		
	Total		747.882	33			

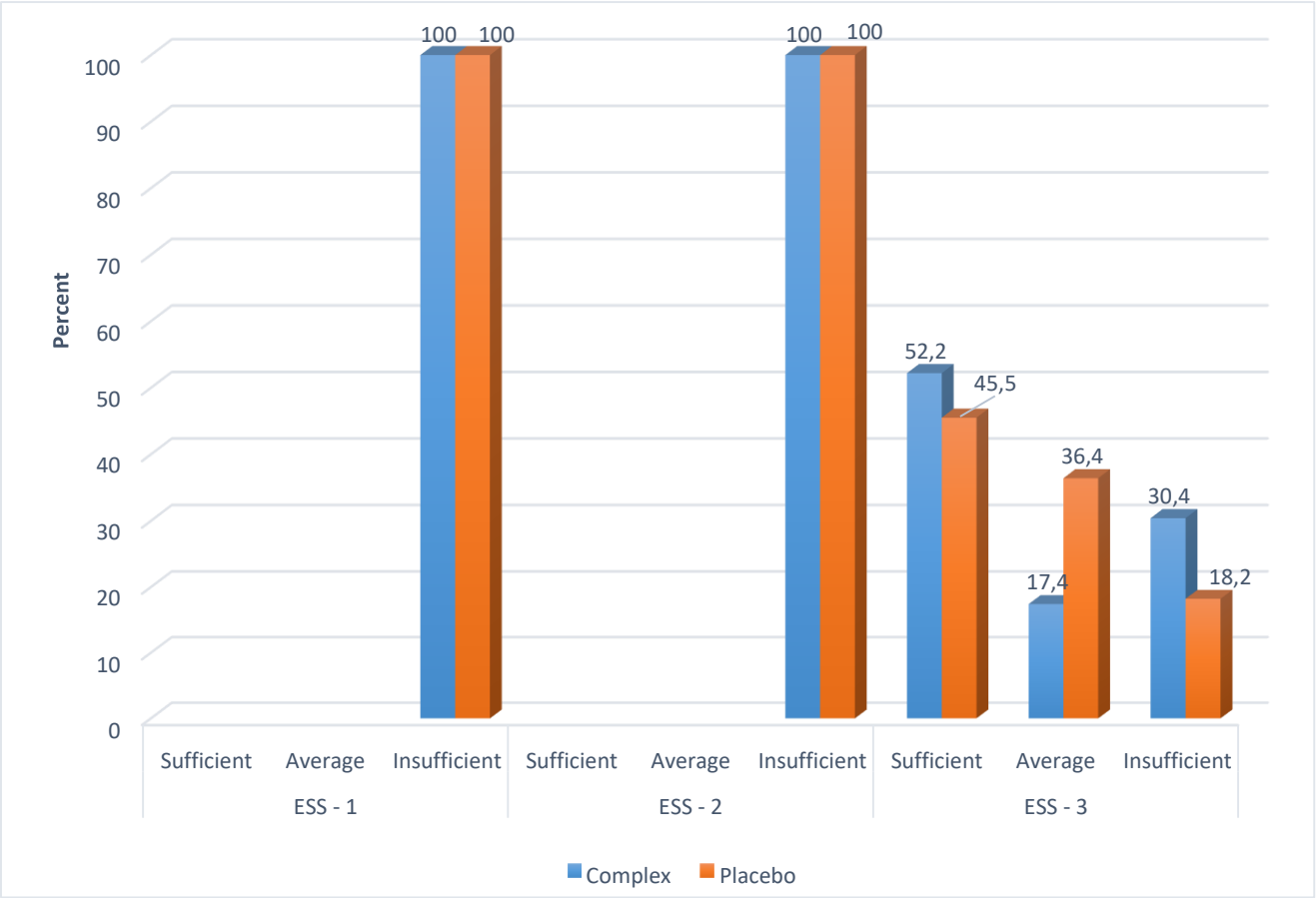

Figure 4.2 Showing the degree of sleep sufficiency of participants

4.6 STANFORD SLEEPINESS SCALE (SSS)

4.6.1 Reliability of the SSS

The combined reliability scores by week is shown in Table 4.11. The scores exceed the recommended value of 0.700. This implies a high degree of consistent scoring in the survey.

Table 4.17 Survey scales and Predictor variables in Stanford Sleepiness Scale

Survey scales	Predictor variables	**Number of Items**	**Cronbach's Alpha score**
1	Week 1	126	0.915
2	Week 2	126	0.865
3	Week 3	126	0.969

4.6.2 SSS Comparison of Means

To determine whether parametric tests could be used, a One-Sample KolmogorovSmirnov Test was done. The normal distribution of the Stanford sleepiness scale reading by weeks is presented in Table 4.18. The One-Sample Kolmogorov-Smirnov test for the normality revealed no significant differences against the normality of the variables ($p > 0.05$). Hence it can be inferred that the distributions are normal and that the t-test and ANOVA can be used.

Table 4.18: One-Sample Kolmogorov-Smirnov Test

		Week 1	Week 2	Week 3
N		35	35	35
Normal Parameters[a,b]	Mean	4.3114	4.2914	4.2571
	Std. Deviation	1.08486	.98857	.91757
Most Extreme Differences	Absolute	.138	.128	.119
	Positive	.129	.111	.106
	Negative	-.138	-.128	-.119
Test Statistic		.138	.128	.119
Asymp. Sig. (2-tailed)		.091[c]	.160[c]	.200[c,d]

a. Test distribution is Normal.
b. Calculated from data.
c. Lilliefors Significance Correction.
d. This is a lower bound of the true significance.

4.6.3 SSS Intra Group analysis

4.6.3.1 SSS Intra-group analysis of Placebo group

With Table 4.19, it can be gleaned that the paired sample analysis of the respondents Stanford sleepiness scale by weeks revealed a strong correlation for all the samples. This implies that there is a positive relationship between all the groups. The t-test analysis in Table 4.14, however revealed no significant differences in the Stanford sleepiness scale analysis by weeks for the Placebo Group ($p > 0.05$) suggesting that there was no significant difference in SSS scores within this group over the three-week study period.

Table 4.19: Placebo Stanford sleepiness scale Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean	Correlation	Sig.
Pair 1	Week 1	4.0833	12	1.52663	.44070	.997	.000
	Week 2	4.0750	12	1.39618	.40304		
Pair 2	Week 1	4.0833	12	1.52663	.44070	.984	.000
	Week 3	4.0917	12	1.28662	.37141		
Pair 3	Week 2	4.0750	12	1.39618	.40304	.993	.000
	Week 3	4.0917	12	1.28662	.37141		

Table 4.20: Independent Paired Samples Test for Placebo Stanford sleepiness scale

		Paired Differences					t	Df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	Week 1 - Week 2	.00833	.16765	.04840	-.09819	.11485	.172	11	.866
Pair 2	Week 1 - Week 3	-.00833	.34499	.09959	-.22753	.21086	-.084	11	.935
Pair 3	Week 2 - Week 3	-.01667	.18990	.05482	-.13732	.10399	-.304	11	.767

4.6.3.2 SSS Intra-group analysis of Homoeopathic Complex group

In terms of the Homoeopathic Complex intra-group analysis, similar trends to that of the Placebo group were observed for both the correlation analysis in Table 4.21 and t-test (Table 4.22). However, with regard to Pair 3 (Week 2 vs Week 3) one can observe that the p value was close to the level of significance p= 0.059).

Table 4.21: Complex Stanford sleepiness scale Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean	Correlation	Sig.
Pair 1	Week 1	4.4304	23	.78128	.16291	.984	.000
	Week 2	4.4043	23	.70484	.14697		
Pair 2						.936	.000
	Week 1	4.3435	23	.67138	.13999		
Pair 3	Week 2	4.4043	23	.70484	.14697	.978	.000
	Week 3	4.3435	23	.67138	.13999		

Table 4.22: Independent Paired Samples Test for Complex Stanford sleepiness scale

		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference			df	Sig. (2tailed)
					Lower	Upper			
Pair 1	Week 1 - Week 2	.02609	.15438	.03219	-.04067	.09285	.810	22	.426
Pair 2	Week 1 - Week 3	.08696	.28172	.05874	-.03487	.20878	1.480	22	.153
Pair 3	Week 2 - Week 3	.06087	.14690	.03063	-.00266	.12440	1.987	22	.059*

4.6.4 SSS Inter Group Comparison

The inter-group relationship of the participants for the Stanford sleepiness scale for both Placebo and Homoeopathic Complex groups by weeks is explained in this section.

The Leven's test for equality of variance, and t-test are shown in Table 4.23. As indicated by the levels of significance, both Leven's test and t-test revealed that the inter-group analysis of SSS data exhibited no statistically significant differences by week between the Homoeopathic Complex and Placebo groups (p>0.05). Notwithstanding this, it can be gathered from Table 4.24 that the mean value for the Homoeopathic Complex inter-group were consistently higher than the Placebo Group for all the weeks.

Table 4.23 Independent Inter-Group Paired Samples Test for Stanford sleepiness scale

		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	Df	Sig. (2tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
Week 1	Equal variances assumed	2.532	.121	.896	33	.377	.34710	.38745	-.44118	1.13538
	Equal variances not assumed			.739	14.080	.472	.34710	.46985	-.66008	1.35428
Week 2	Equal variances assumed	2.673	.112	.934	33	.357	.32935	.35270	-.38823	1.04693
	Equal variances not assumed			.768	13.996	.455	.32935	.42900	-.59080	1.24949
Week 3	Equal variances assumed	2.717	.109	.766	33	.449	.25181	.32876	-.41705	.92067
	Equal variances not assumed			.634	14.204	.536	.25181	.39692	-.59835	1.10198

Table 4.24: Complex Stanford sleepiness scale Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean	Correlation	Sig.
Pair 1	Week 1	4.4304	23	.78128	.16291	.984	.000
	Week 2	4.4043	23	.70484	.14697		
Pair 2	Week	4.43	23	.78128		.936	.000
	Week 3	4.3435	23	.67138	.13999		
Pair 3	Week 2	4.4043	23	.70484	.14697	.978	.000
	Week 3	4.3435	23	.67138	.13999		

Table 4.25: Independent Paired Samples Test for Complex Stanford sleepiness scale

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	Week 1 - Week 2	.02609	.15438	.03219	-.04067	.09285	.810	22	.426
Pair 2	Week 1 - Week 3	.08696	.28172	.05874	-.03487	.20878	1.480	22	.153
Pair 3	Week 2 - Week 3	.06087	.14690	.03063	-.00266	.12440	1.987	22	.059*

Table 4.26: Mean, standard deviation, stand error Inter-Group test

	Group	N	Mean	Std. Deviation	Std. Error Mean
Week 1	Complex	23	4.4304	.78128	.16291
	Placebo	12	4.0833	1.52663	.44070
Week 2	complex	23		.70484	.146973
	Placebo	12	4.0750	1.39618	.40304
Week 3	Complex	23	4.3435	.67138	.13999
	Placebo	12	4.0917	1.28662	.37141

More so, the Fischer exact test score shown in Table 4.25 revealed no significant differences between groups in all weeks ($p>0.05$). Despite this, and as summarised in Figure 4.3, it can be observed that there is a subtle difference in the respondents scoring pattern. In Figure 4.3 SSS Scores of 1-3 during working hours was classified as being sufficiently alert and scores of 3-7 during working hours classified as being insufficiently alert (sleepy).

Within the Homoeopathic Complex Group, the percentage of those who were insufficiently alert reduced over time and the percentage who were sufficiency alert in increased over time However the percentage of those in the placebo group who were insufficiently alert and those who were insufficiently alert remained unchanged throughout the study suggesting no change in response to Placebo.

Such suggestions are supported by Figure 4.4 comparing means of the respective groups over the three measurement intervals. Despite this subtle yet interesting trend there was no statistically significant difference between the Homoeopathic Complex and Placebo Groups with respect to SSS scores.

Table 4.27 Inter-Group Fisher exact test

		Complex	Placebo	Fisher's Exact Test
W1	Insufficient	34.8%	41.7%	0.726
	Sufficient	65.2%	58.3%	
W2	Insufficient	34.8%	41.7%	0.726
	Sufficient	65.2%	58.3%	
W3	Insufficient	30.4%	41.7%	0.709
	Sufficient	69.6%	58.3%	

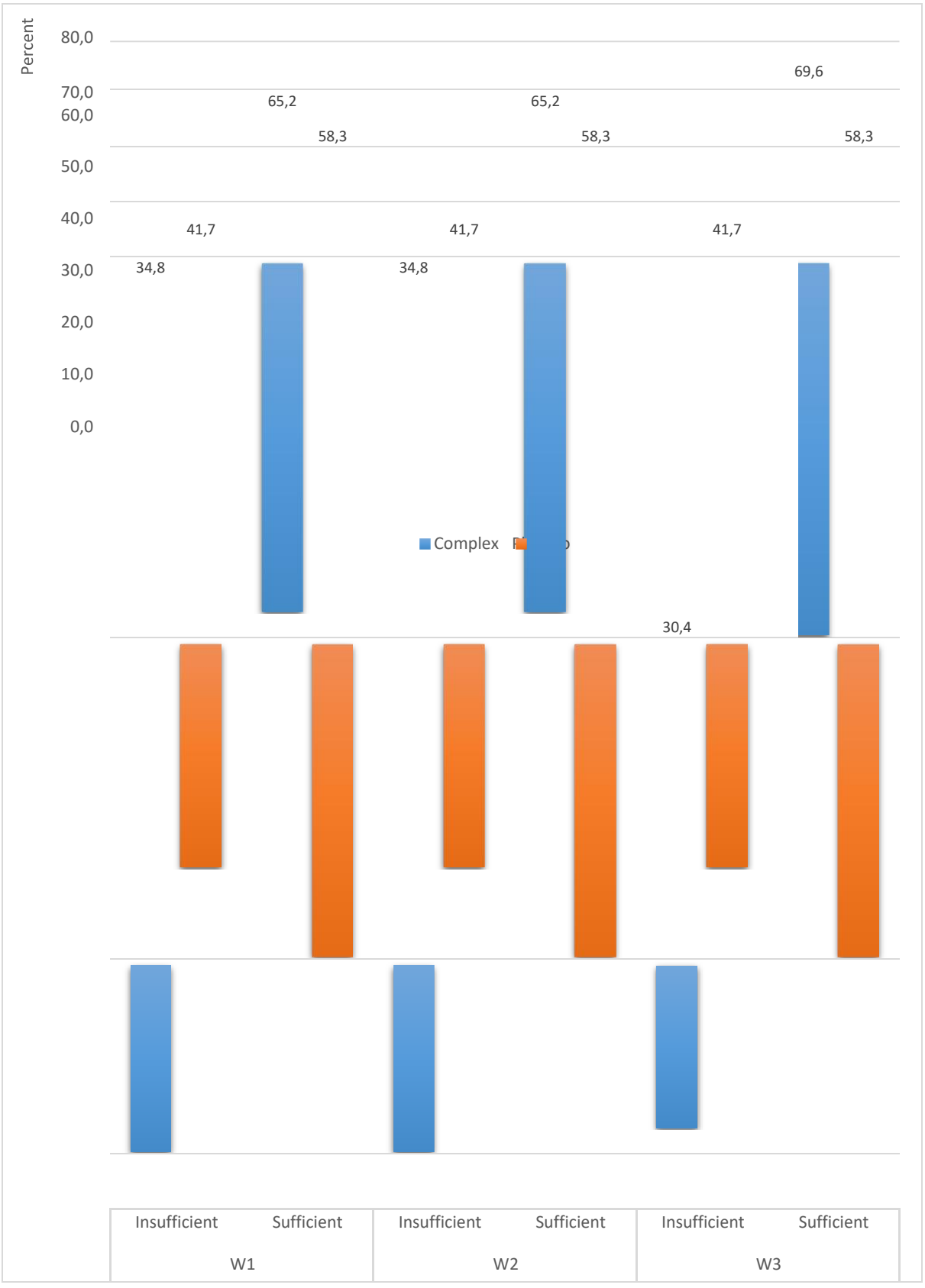

Figure 4.4 Comparison of SSS Mean Scores across the three measurement intervals

Figure 4-3: Showing the participant's assessment of both Placebo and Complex on the Stanford sleepiness scale by weeks. Figure 4.4 Comparison of SSS Mean Scores across the three measurement intervals

4.7 CONCLUSIONS

Intra group analyses of ESS means revealed that both groups improved significantly over time i.e. were less sleepy at the conclusion of the study; intergroup ANOVA analyses however did not confirm any significant difference between the ESS scores of the respective groups suggesting that the improvement noted within groups was similar between groups thus neither intervention appeared to be superior to the other.

Section analyses using Fisher's Exact Tests did however reveal statistically significant differences in ESS_5 and ESS_8 variables at close out (ESS_3) – such differences were in favour of the Homoeopathic Complex group being less sleepy in the respective settings. Although when data was arranged into categories of sleepiness and compared the Homoeopathic Complex group had a larger portion of participants who were less sleepy the ESS intergroup ANOVA analysis revealed no significant differences between the groups.

Intra-group analyses of SSS data revealed no statistically significant change in SSS scores over the three study weeks in both the Homoeopathic Complex and the Placebo Groups – when comparing Week 2 with Week 3 within the Homoeopathic Complex Group though statistical significance was almost reached P=0.059 suggesting possible improvement in SSS scores in this group. Inter-group Fischer's Exact tests revealed no statistically significant differences between the groups across the three weeks the data did demonstrate that the percentage of those who were insufficiently alert decreased in the Homoeopathic Complex group and the percentage of those who were sufficiently alert increased over time – this trend was not seen in the Placebo Group.

The next chapter will provide the conclusions drawn from this study. This will include the identification of limitations, which will steer the study for future research.

CHAPTER FIVE

DISCUSSION

5.1 INTRODUCTION

The aim of this randomised, double-blind placebo controlled study was to determine the efficacy of a homoeopathic complex (Nux moschata D6, Phosphoricum acidum D30, Helliborus niger D6, Opium D30) compared to placebo in the management of Excessive Daytime Sleepiness in terms of the Epworth Sleepiness Scale (ESS) (Johns 1991) and the Stanford Sleepiness Scale (SSS) (Hoddes et al. 1973).

5.2 DEMOGRAPHICS AND SAMPLE

A total of 35 participants between the ages of 18 to 30 were recruited and they were randomly assigned to either an experimental (homoeopathic complex) or control (placebo) group, according to the method and criterion in section 3.1 – 3.4. The experimental group consisted of 23 participants, 11 males and 12 females and the placebo group consisted of 12 participants; 4 males and 8 females (table 4.1). Demographic data from the current study revealed a limited age range, this is to be expected as the inclusion criteria limited age range from 18-30yrs. In terms of gender distribution, the experimental group had more males i.e.11 males (4 males in the placebo group) and the entire sample was 43% male and 57% female. Existing literature too reports a higher prevalence amongst females than males; (Hayley et al. 2014) reported prevalence of EDS in Australians of similar age range (20-29yrs) to be 5.1% male and 14.7% in females and according to (Joo et al. 2009) the prevalence of EDS for Asians in Korea was 10.7% in males and 13.7%, and according to (Fatani et. al. 2015) in the Saudi population young females (ages 29 years or less) had higher levels of EDS than young males (37.7% vs 22.1%). Furthermore, the study showed that females were twice more likely to have EDS compared to young males as they showed to have shorter hours of sleep per night and more hours of sleep during the day.

5.3 THE EPWORTH SLEEPINESS SCALE (ESS) DATA

The Epworth Sleepiness Scale (Smyth 2012) scores were reliable as it had a high level of internal consistency between the eight items as measured by Cronbach's alpha score. Assessment of scores for both groups combined (Table 4.4) revealed an acceptable reliability coefficient of 0.798. Hayley et al. (2014) found the ESS tool to be reliable as he stated that its use is advantageous for population based research and he also considered it an effective tool for differentiating sleepiness amongst a varied population. Hayley et al. (2014) also stated that many studies have chosen the ESS as a measurement tool in indicating pathological levels of sleepiness. According to Johns (2014) the ESS has become the world standard method for measuring the general levels of daytime sleepiness or the average sleep propensity in daily life; the results of the ESS are found to be reliable and of advantage because it is very simple to administer to a large number of people (Johns 2014).

The One-Sample Kolmogorov-Smirnov test revealed (that the ESS data was normally distributed which allowed for parametric statistical analysis to be applied. (See Table 4.6)

Intra-group analyses of ESS total score means for both the placebo group and homoeopathic complex group using the independent Paired Samples Test revealed statistically significant differences between pre and post treatment scores (see tables 4.12 and 4.14 respectively) i.e. $p<0.05$; both groups were significantly less sleepy in terms of ESS total scores at the conclusion of the study.

Although both groups achieved statistically significant reductions in ESS total scores when comparing pre and post treatment means, only in the homoeopathic complex group were such finding supported by correlation scores (see table 4.13) i.e. in the homoeopathic complex group there was correlation between the two baseline scores but no correlation between pre and post treatment scores. In the placebo group although statistically dissimilar in terms, Independent Paired Samples Tests the pre and post treatment means correlated (Table 4.11).

Section analyses of individual variables within the ESS between groups revealed statistically significance differences in two of the eight variables between the homoeopathic complex and placebo groups, such differences were noted between

close out scores for variables 5 (p=0.020) and 8 (p=0.019) (Table 4.9) and in favour of the homeopathic complex group i.e. those in the homoeopathic complex group were significantly less likely to doze off when lying down to rest in the afternoon when circumstances permitted and less likely to doze off in a car while stopped in traffic for a few minutes; the latter is particularly is clinically relevant given the links between EDS and motor vehicle accidents (Pagel 2009).

Inter group ANOVA analyses revealed no significant difference between total ESS scores at any of the three measurement intervals suggesting that homoeopathic complex and placebo scores were similar throughout the study (Table 4.16).

When ESS scores were grouped into three categories of varying degrees of sleepiness and compared at the post treatment stage it was noted that 52% of those in the homoeopathic complex group had ESS scores of 6 or less (slightly sleepy) and only 45% of those in the placebo group had scores of 6 or less, although statically dissimilar in terms of ANOVA analyses such data and that of the Fisher's exact section analyses are suggest that the homoeopathic complex was superior to placebo in terms of ESS scores.

There were no statistical differences between the Homoeopathic complex and the placebo group at recruitment, baseline and at close out, this revealed that the means were not statistically different from each other. And the results revealed that at recruitment and baseline, 100% of the participants of both groups we classified as very sleepy/ severe, whereas at close out there were significant differences between the results of the complex and the placebo group, as most of the participants on the complex group (Table 4.9) were slightly sleepy compared to those of the placebo group, and more participants in the placebo group were moderately sleepy at close out compared to the complex group.

The objective of the study was to determine the efficacy of a homoeopathic complex in the management of EDS in terms of the Epworth Sleepiness Scale (ESS); and the ESS means revealed that there was not much difference between both as the participants of both groups were less sleepy by the end of the study, in addition the ANOVA inter group analysis did not confirm any significant differences between the ESS scores of the homoeopathic complex and placebo groups. Non withstanding such statistical findings the Homoeopathic Complex group had a larger portion of

participants who were less sleepy at the end of the study and the Fisher's Exact section analysis revealed two variables which differed significantly at post treatment measurement in favour of the homoeopathic complex treatment. A holistic review of the ESS data in such a manner is suggestive of some degree of efficacy of the homoeopathic complex over placebo, and minimally a clinical significance is noted particularly with respect to the two differing variables revealed by the Fisher's Exact factor analysis.

5.4 THE STANDFORD SLEEPINESS SCALE (ESS) DATA

The Stanford Sleepiness Scale (SSS) (Hoddes et al. 1973) measured how alert the participants were during the course of the day before and after treatment.

Reliability measures (Cronbach Alpha Scores) (Table 4.11) of SSS data all confirmed a high degree of consistency of the SSS data confirming the reliability of the SSS measurement tool. The results from this study were found to be reliable as the participants rated themselves in a similar manner as the participants of the previous study that was conducted by (Bailes, Libman et al. 2006). The findings of this study with regard to reliability of the SSS concur with previous findings (Shahid, et al) (Herscovitch & Broughton, 1981). As with the ESS data the data gleaned from the SSS measurements was determined to be normally distributed according to the One Sample Kolmogorov Smirnov tests revealed that there were no significant differences against the normality of variables as $p > 0.05$ (As seen in Table 4.18 with the normal distribution of Stanford sleepiness scale by week).
Within the placebo group and the complex group seen in Table 4.19 a strong correlation for all samples was observed for the Stanford sleepiness scale, thus there was a positive relationship between the groups however t-tests showed that the SSS scores did not change significantly during the study period i.e. all p values were significantly higher that 0.05 (Table 4.20) this suggests that in terms of the SSS the participants sleepiness clearly did not change in response to placebo.

Within the homoeopathic complex groups, a strong correlation for all samples was observed in a similar trend as to the placebo group (Table 4.21 and Table 4.22). SSS scores did not differ significantly over the study period however when comparing week 2 and week 3 the difference here was almost statistically significant

(p=0.059) although considered a weak level of significance this p-value could infer some degree of improvement in SSS scores by the end of the study and thus may be clinically significant.

There were no statistical differences when SSS scores were compared between both the homoeopathic complex group and the placebo group in terms of the Fisher exact test (p>0.05) (Table 4.25). However, when one compares the scoring patterns between groups (Figure 4.3) one can observe that within the complex group the percentage of participants classified as having 'sufficient' levels of alertness (low level of sleepiness) increases by 4% by the end of the study and the percentage of those classified as having 'insufficient' levels of alertness decreases by 4% respectively this trend is suggesting that those in the complex group improved slightly in terms of SSS scores. Within the placebo group however the same figure clearly shows the contrary i.e. the percentage classified as having 'sufficient' and 'insufficient' levels of alertness did not change throughout the study this clearly suggests that there was no response to the placebo intervention. This is an interesting observation and suggests that the homoeopathic complex had a positive impact on the level of sleepiness of participants and appeared to be superior to the placebo.

The objective of the study was to also determine the efficacy of a homoeopathic complex in the management of EDS in terms of the Stanford Sleepiness Scale (SSS), and the intergroup analysis of the SSS also revealed that there was no statistically significant change between both groups, but they were some improvement when comparing Week 2 with Week 3 within the Homoeopathic Complex Group as the statistical significance was almost reached. And the Inter-group Fischer's Exact tests revealed no statistically significant differences between both groups, but it was noted that those who were insufficiently alert decreased in the Homoeopathic Complex group and the percentage of those who were sufficiently alert increased over time but this was not seen in the Placebo Group.

5.5 SUMMARY

In summary we can conclude that both groups improved in terms of total ESS scores it appears however that this degree of improvement was equal between groups i.e. they both improved equally, however in terms of two of the individual variables of the ESS the homoeopathic complex demonstrated superiority over placebo in reducing respective ESS score suggesting the complex having a beneficial effect on sleepiness in these two settings. A further trend of clinical significance in support of the homoeopathic complex was revealed when categorising levels of sleepiness; the homoeopathic complex having a larger portion who were less sleepy, this despite inter-group analyses confirming no difference between the groups.

SSS scores did not change in response to placebo, however in response to homoeopathic complex a p value of 0.059 suggesting a weak level of significance suggested that there was some small degree of improvement in response to homoeopathic complex within this group. Although there was no statistically significant difference between groups in terms of SSS scores a comparison of scoring patterns did show a decline in the percentage of those classified as having an insufficient degree of alertness by 4% and an increase in the percentage of those with sufficient alertness by 4%; this only occurred in the homoeopathic complex group.

CHAPTER SIX

CONCLUSION AND RECOMMANDATIONS

6.1 CONCLUSION

Barring a few exceptions described in Chapter 4 & 5 it can be concluded from the results of the study that statistically the Homoeopathic complex (Nux moschata D6, Phosphoricum acidum D30, Helliborus niger D6, Opium D30) was not superior to placebo in the treatment of EDS. The data shows that both the Homoeopathic Complex and the placebo interventions had a positive effect on EDS and were effective in improving the level of excessive daytime Sleepiness. Irrespective of the general lack of statistical significance between groups a closer analysis of the intragroup and inter-group data does reveal a trend suggesting clinical significance in support of the effectiveness of the homoeopathic complex in the treatment of EDS however this needs to be further explored and confirmed in subsequent studies.

6.1.1 THE FIRST OBJECTIVE

The first objective was to determine the efficacy of a homoeopathic complex in the management of EDS in terms of the Epworth Sleepiness Scale (ESS).

According to ESS data both groups were statistically significantly less sleepy at the end of the study i.e. both interventions had a positive effect on EDS. Section analysis of ESS variables between groups however revealed a significant difference in two variables between groups in favour of the homoeopathic complex but mean total scores analysed between groups by ANOVA showed the groups to be similar at all measurement intervals. Descriptive data analysed in categorical format did suggest however that there was a clinically significant trend suggesting a greater improvement in those within the homoeopathic complex group.

ESS data thus clearly confirms a positive response to the homoeopathic complex however the response arguably was not clearly superior to that of the placebo intervention.

6.1.2 THE SECOND OBJECTIVE

The second objective was to determine the efficacy of a homoeopathic complex in the management of EDS in terms of the Stanford Sleepiness Scale (SSS).

SSS data revealed that there was no significant improvement in response to placebo homoeopathic however a weak statistical significance was seen in the homoeopathic complex group when comparing baseline and close out scores ($p=0.059$).

Inter-group analysis demonstrated no difference in SSS scores between groups, some degree of clinical significance however can be argued when reviewing levels of alertness where a trend of improvement was noted in the homoeopathic complex group but not in the placebo group.

SSS data revealed a weak level of significance suggesting a favourable response to the homoeopathic complex, descriptive data is suggestive of favourable response to the homoeopathic complex but this was not confirmed statistically.

6.1.3 THE BENEFITS OF THE STUDY

Participants benefited in various ways, for most the levels of alertness improved and the levels of sleepiness significantly decreased irrespective of group allocation.

Participants further gained information about Excessive Daytime Sleepiness as a condition, as most of them did not have any knowledge about it, and this helped them improve their lifestyle and change some habits that lead to the effects of the condition, in addition most participants were exposed to homoeopathy for the first time.

6.2 RECOMMENDATIONS

Recommendations for further studies:

1. Future studies should incorporate a larger sample size, as this will result in higher statistical power, ensure a more reliable statistical data and greater external validity.

2. Future studies should be conducted over a significantly longer period it is speculated that a longer treatment period would result in more significant results.

3. Data should be collected after discontinuing the interventions to ascertain if the changes in EDS noted were sustainable such data may show a more rapid regression to baseline in those who received placebo compared to those who received the homoeopathic complex.

4. Future studies treating ESS should focus on collecting data using the ESS as opposed to the SSS as the ESS was more practical to apply and the format of data collected was more suited to determine the outcome of the medicinal intervention.

5. Future studies should review the potencies used in the homeopathic complex as adjustments in potency may result in more significant results.

6. Future Studies should consider potentising the placebo to the same level as the alcohol vehicle used in the remedy as this would be the most accurate way of comparing the outcome from the active remedy and placebo effects.

REFERENCE LIST

American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders. 4th edition. Text revision. 2000. Washington, DC, American Psychiatric Association.

Arble, D., M. 2015. Impact of sleep and cardian disruption on energy balance and diabetes. 38(12): 1849-1860.

Bailes, S., Libman, E., Baltzan, M., Amsel, R., Schondorf, R., Fichten, C.S. 2006. Brief and distinct empirical sleepiness and fatigue scales. Journal of Psychomatic Research. 60: 605-613.

Banerjee, D., Vitiello, M.V., Grunstein, R., R. 2004. Pharmacotherapy for excessive daytime sleepiness. Sleep Medicine. 8: 339-354.

Beers, M.H., Fletcher, A.J., Jones, V.T., Porter, R., Berkwits, M. and Kaplan, J.L. 2003. The Merck Manual of Medical Information. 2nd home edition. Whitehouse Station, N.J: Merck Research Laboratories.

Beers, M.H. and Berkow, R. 1999. The Merck Manual. 17th edition. Whitehouse Station, N.J: Merck Research Laboratories.

Bloch, M. 2002. The efficacy of homoeopathic simillimum in the treatment of nocturnal enuresis in children between five and eighteen years of age who reside in children's homes. Master's Degree in Technology: Homoeopathy, thesis, Durban institute of Technology.

Bloch, R. and Lewis, B. 2003. Homoeopathy for the Home. Cape Town: South Africa: Stuik Publishers.

Boerike, W. 2008. Boericke's New Manual of Homoeopathic Materia Medica. New Deli: B. Jain Publishers.

British Homoeopathic Association (Ed.). 1991. German Homoeopathic Pharmacopoeia (G.H.P). 5th Supplement to the first edition: 39.

Carlston, M. 2003. Classical Homeopathy. Philadelphia: Churchill Livingstone.

Chauhan, VK. and Gupta, M. 2007. Homoeopathic principles and practice of medicine: Homoeopathic fundaments.1st ed. India: B. Jain publishers.

Coppola, L., Montanaro, F. 2013. Effect of a homoeopathic complex medicine on state and trait anxiety and sleep disorders: a retrospective observational study. Department of Dietary Nutrition and complementary medicine. 102, 254 – 261.

De Schepper, L. 2001. Hahnemann Revisited: A textbook of Classical Homeopathy for the Professional. Santa Fe: Full of Life Publications.

De Schepper, L. 2001. Hahnemann Revisited. United States of America: Full of life Publishers.

DOH. Health, D. O. 2004. Ethics in Health Research: Principles, Structures and Processes - Research Ethics Guidelines. Pretoria: Department of Health.

Dorland's Illustrated Medical Dictionary. 28th edition. 1994. Philadelphia: W B Saunders Company.

Driehsen, W. 2003. German Homoeopathic Pharmacopoeia. Stuttgart: Medpharm Scientific Publishers.

Dworzański W, Opielak G, Burdan F. 2011. Side effects of caffeine. 161: 357-361.

Eizayaga, F.X. 1991. Treatise on Homoeopathic Medicine. Buenos Aires. Ediciones Marecel.

Fatani, A., J., Abvohashish, H., M., Ahmed, M., M. 2015. Lutein dietary supplementation attenuates. BMC complementary and alternative medicine.2015:204.

Fong, S.Y.Y., Ho, C.K.W., Wing, Y.K. 2005. Comparing MSLT and ESS in the measurement of excessive daytime sleepiness in obstructive sleep apnoea syndrome. Journal of Psychosomatic Research. 58: 55-60

Gaier, H. 1991. Thorsons Encycloedic Dicionary of Homoeopathy: The Definitive Reference to all aspects of Homoeopathy. London. U.K: Harper Collins.

Guyton, A.C., and Hall, J.E. 1997. Human Physiology and Mechanisms of Disease. 6th Edition. Philadelphia: W.B. Saunders Company.

Haslett, C., Chilvers, E.R., Hunter, J.A.A. and Boon, N.A.1999. Davidson's Principles and Practice of Medicine. 18th Edition. Edinburgh: Churchill Livingstone.

Hayley, A.C., Williams, L.J., Kennedy, GA., Berk, M., Brennan, A.L., Pasco, A.A. 2014. Prevalence of excessive daytime sleepiness in a sample of Australian adult population. Sleep Medicine. 15: 348-354.

Hering, C. 2013. Nux moschata in excessive day time sleepiness (online). Available: http://www.hpathy.com/e-books/guiding-symptoms-of-our-materia-medica/nuxmoschata-4/ (Accessed 7 February 2016)

Hoddes, E., Zarcone, V., Smythe, H., Phillips, R. and Dement, W.C. 1973. Quantification of Sleepiness: A New Approach. Psychophysiology, 10(4): 431 – 436

Hayley, A.C., Williams, L.J., Kennedy, GA., Berk, M., Brennan, A.L., Pasco, A.A. 2014. Prevalence of excessive daytime sleepiness in a sample of Australian adult population. Sleep Medicine. 15: 348-354.

Herscovitch, J., Broughton, R. 1981. Sensitivity of the Stanford sleepiness scale to the effects of cumulative partial sleep deprivation and recovery oversleeping. PubMed, 4(1):83-91.

Hoddes, E., Zarcone, V., Smythe, H., Phillips, R. and Dement, W. 1973. Quantification of Sleepiness: A New Approach. Psychophysiology Methodology, 10 (4): 431-436.

Hübner, R., van Haselen, R., Klein, P. 2009. Effectiveness of the Homeopathic Preparation Neurexan® Compared with that of Commonly used Valarian-Based Prepatations for the Treatment of Nervousness/Restlessness – an observaitonal study. The Scientific World Journal.9:733-745.

ICD10Data.Diagnosis Codes>Diseases of the nervous system(online).2016. Available: http://www.icd10data.com/icd10cm/codes/G00-G99/G40-G47/47.10.com

Johns, M.J. 1991. A New Method for Measuring Daytime Sleepiness: The Epworth Sleepiness Scale. Sleep. 14(6): 540-545

Johns, M.W. 1991. A new method for measuring daytime sleepiness. The Epworth Test. Sleep. 14(6); 540-545.

Joo. A., Baik, I., Yi, H., Jung, K., Kim, J., Shin, C. 2009. Prevalence of excessive daytime sleepiness and associated factors in the adult population in Korea. Sleep Medicine. 10: 182-188.

Jouanny, J. 1993.The Essentials of Homoeopathic Therapeutics.
Sainte - Foy - Les - Lyon: Editions Boiron. 417.

Kayne, S.B. 2006. Homeopathic Pharmacy – Theory and Practice. 2nd Ed.
Philadelphia: Elsevier Churchill Livingstone.

Kayne, S.B. 1997. Homoeopathic Pharmacy. An Introduction and Handbook.
Edinburgh: Churchill Livingstone.

Klepser, T.B. and Klepser, M.E. 1999. Unsafe and Potentially Safe Herbal Remedies.
American Journal of Health System Pharmacy, 56: 125 – 138.

Kryger, M.H., Roth, T., and Dement, W.C. 1998, Principles and Practice of Sleep Medicine. 2nd edition. Philadelphia: W.B Saunders Company.

Laurence, D.R. and Carpenter, J.R. 1994. A Dictionary of Pharmacology and Clinical Drug Evolution. London: UCL Press Limited. ISBN 1 85728 1128. Lavery, S. 1997. The Healing Power of Sleep. Meeus, C., Gaia Books Limited.

Leckridge, B .1997. Homoeopathy in Primary Health Care. Churchill Livingston.
(11):15-20.

Marian, F. Joost, K.D Saini, Von Ammon,K. Thurneysen, A and Busato, A.2008. Patient satisfaction and side effects in primary care: An observational study comparing homoeopathy and conventional medicine. BMC Complementary and alternative Medicine [Online], 8(52). Available at: http://www.biomedcentral.com/1472-6882/8/52 [Accessed 10 March 2015].

Mayo Clinic. 2014. Disease and conditions (online). Available: http://www.mayoclinic.org/diseases-conditions. (Accessed 2015/12/14).

Mayo Clinic. 2014. Interpretive Handbook: Glutamic Acid Decarboxylase (GAD65) Antibody Assay, Serum. Clinical Information (online). Available: http://www.mayomedicallaboratories.com/interpretive. (Accessed 2015/12/14)

Medline Plus. 2014. Health Topics (online). Available: https://www.nlm.nih.gov/medlineplus/healthtopics.html. (Accessed 2015/12/14)

Mercer, S., Reilly D. 2004. A qualitative study of patient's views on the consultation at the Glasgow Homoeopathic Hospital, an NHS integrative complementary and orthodox medical care unit. Patient Education and Counselling, 53:13–18.

Morrison, I. and Riha, R. 2012. Excessive daytime sleepiness and narcolepsy - An approach to investigation and management. European Journal of Internal Medicine, 12: 110-117.

Mouton, J. E., 2001, The Practice of Social Research, Cape Town: Oxford University Press, 10: 221-230

Müller-Löbnitz, C., Göthel. D. Review of the Clinical Efficacy of the Multicomponent Combination Medication Traumeel and Its Components. Alternative Therapies. 17:2 – S18-S31.

Murphy, R. 2003. Homeopathic remedy guide. Encyclopaedia Homeopathica, version, 2: 0069.

Narcolepsy (online). 2009.Available: http://www.nisformacolepsy.com/. (Accessed 14 August 2014)

O'Reilly W.B. 1996. Organon of the Medical Art by DR. SAMUEL HAHNEMANN. California. Birdcage

Osawa, B. 2001. The Principles of Homoeopathic Philosophy. Simillimum. 14:24.

Pagel, J. 2009. Excessive Daytime Sleepiness. American Family Physician, 79 (5): 391-396.

Peters, D. 2001. Understanding the Placebo Effect in Complementary Medicine. Edinburgh: Churchill Livingstone.

Phatak, S. R. 1999. Materia medica of homoeopathic medicine. 7th ed. India: B. Jain Publishers.

Phatak, S.R. 2002. Materia Medica of Homoeopathic Medicines. New Deli: B.Jain Publishers.

Pillay, S. 2013. A study on the knowledge, attitudes and perceptions of primary healthcare nurses in the eThekwini municipality district with regards to the inclusion of homoeopathy in the primary healthcare. M Tech: Homeopathy mini-dissertation. Durban University of Technology.

Plate, D., T. 2.15. Hypersomnia in mood disorders: a rapidly changing landscape. 1(2): 122-130.

Rossi, E., Di Stefano, M., Baccetti, S., Firenzuoli, F., Verdone, M., Facchini, M., Stambolovich, V., Vina, M. P. & Clades, M. J. 2010. International cooperation in support of homoeopathy and complementary medicine in developing countries: The Tuscan experience. Homoeopathy, 99: 278-283.

Sankaran, R.1994. The Substance of Homoeopathy. Mumbai: Homoeopathic Medical Publishers.

Sankaran, R.1991.The Science of Healing. New Delhi: B.Jain Publishers Pvt. Ltd.

Sara M. Seifert, Judith L. Schaechter, Eugene R. Hershorin, Steven E. Lipshultz. 2011.
Health Effects of Energy Drinks on Children, Adolescents, and Young Adults.
American academy of paediatrics. 1:1-2.
School of Homeopathy, 2004. Proving procedures and guidelines for provers and supervisors [online]. Available at: http://www.hominf.org/articles/miprots.htm (Accessed 14 August 2014)

Schneider, C. 2011. Traumeel – an emerging option to nonsteroidal – antiinflammatory drugs in the management of acute musculoskeletal injuries. International Journal of General Medicine. 4: 225-234.

Shahid, A., Shen, J., Shapiro, C. M. 2010. Measurements of sleepiness and fatigue (online). Available: http://dxdol.org/10.1016/J.psychores.2010.04.001 (Accessed 9 February 2016).

Shepherd, S. (ed.) 1999. Reader's Digest. The Healing Power of Vitamins, Minerals and Herbs. Newlands: Heritage Publishers. 416.

Silverman, D. 2007. Qualitative research: theory, method and practice. London. Sage.

Singh, P. Ydav, R.J and Pandey, A.2005. Utilization of indigenous systems of medicine and homoeopathy. Indian J med res [Online], 122(2): 137-42. Available at: http://www.ncbi.nlm.nih.gov/m/pubmed/16177471/ [Accessed 10 March 2014].

Singh, V. Harries, C. and Naidoo, DM. 2004. Prevalence, patterns of usage and people's attitudes towards complementary and alternative medicine amongst the Indian community in Chatsworth, South Africa. M Tech: Homeopathy minidissertation. Durban University of Technology.

Smyth, C. 2012. The Epworth Sleepiness Scale. Try this. 6:2.

Stadman, T., L. 2002. Stedman's Medical Dictionary for the health proffesion and nursing. Philadelphia. Lippincott Williams and Wilkins.

Stanford University. 2010.The Stanford Sleeping Scale. Available: http://stanford.edu/dement/sss.htmi (Accessed 11 June 2014).

Sureshbabu, S., Muniem, A., Bhetia, M. 2016. Diagnosis and management of narcolepsy in the Indian scenario, 19(4): 456-461.

Swayne, J. 1998. Homoeopathic Method: Implications for Clinical Practice and Medical science. Edinburgh. Churchill Livingstone.

Swayne, J. 2000. Churchill Livingstone's Inter/national Dictionary of Homeopathy. London: Churchill Livingstone, an imprint of Harcourt Publishers Ltd.

Tetyana Pudrovska. 2013. Excessive daytime sleepiness. National institute of health. 92: 1–24.

The Epworth test. 2010.Available: http://epworth.edu/-dement/sss.htmi/. (Accessed 15 August 2014)

Thorpy, M.2016.Sleep hygiene. Available: http://www.sleepyfoundation.org/ask-theexpect/sleephygiene.com (Accessed 17 April 2016).

Towsey, M.W. and Hasan, M.Y. 1995. Homoeopathy – a biophysical point of view. British Homoeopathic Journal, 84: 227.

Ullmann, D.1991. Discovering Homoeopathy. Berkley: North Atllantic Book.

WMA Declaration of Helsinki.2008. Ethical Principles for Medical Research Involving Human Subjects. Available: http://www.wma.net/en/30publications/10policies/b3/.com (Accessed 11 June 2014)

Van den Meerschaut, L., Sünder, A. 2009. The Homeopathic Preparation Nervoheel N can offer an alternative to Lorazepam Therapy for Mild Nervous Disorders. eCAM. 6 (4)507-515.

Verlag, D.A.2003.German Homoeopathic Pharmacopeia.5th ed. South Africa: Medpharm publishers.

Vithoulkas, G. 1986. The Science of Homoeopathy: The classic homoeopathy textbook. London: Thorsons.

Vithoulkas, G. 2001. Editorial: A proving of Thiosamine. British Homoeopathic Journal, 90(July): 172.

Vithoulkas, G. 2002. The Science of Homoeopathy. New Delhi: B. Jain Publishers.

World Health Organization (WHO). 2011. A report on Excessive Daytime Sleepiness.

Yasgur, J. 1997. Homoeopathic Dictionary and Holistic Health References. Greenville, USA: Van Hoy Publishers.

Appendices

Appendix A: Advert

Sleepy during the day?

Are you a Tertiary student suffering from Excessive Daytime Sleepiness?

Research on this topic is being conducted at the DUT Homeopathic Day Clinic as part of three M. Tech: Homoeopathy studies.

If you are interested in participating and to see if you qualify please contact:

Nondumiso Shabangu 076 1129 187

The homoeopathic clinic 031 373 2041

Appendix B: Letter of Information

LETTER OF INFORMATION

Title of the Research Study: The efficacy of a homoeopathic complex *(Nux moschata D6, Phosphoricum acidum D30, Helliborus niger D6, Opium D30)* in the management of excessive daytime sleepiness.

Principal Investigator/s/researcher: (Name, qualifications)
Nondumiso Shabangu – Bachelor's Degree in Technology: Homoeopathy

Co-Investigator/s/supervisor/s: (Name, qualifications)

Dr David Naude – Master's Degree in Technology: Homoeopathy

Thank you for showing interest in this study.

Brief Introduction and Purpose of the Study:
The reason for this study is to test a homoeopathic medicine on a common problem called Excessive Daytime Sleepiness (EDS). EDS is a condition where you feel sleepy or tired during the daytime when you should be alert.

Outline of the Procedures:
If you voluntarily respond to one of our advertisements on campus we will call you back and with your permission ask you a series of short questions to see if you are a suitable participant for the research, this should take less than 5 minutes, we will also answer any questions you may have regarding the study – we are only including 30 participants in this study and once we have obtained 30 we will not take in any further participants.

You qualify to participate in this study if you must:

- Be between 18 and 30 years of age
- Be a registered tertiary education student
- Be willing to follow the respective research process including 3 consultations with the researcher as well as comply with the research protocol and provide written informed consent (give us your permission in writing confirming you want to participate)
- Be in a general good state of health
- Have a ESS score of greater or equal to 10 [which suggests excessive sleepiness] – this is a questionnaire we will complete with you when we see you.

We cannot include you if you:

- Are younger than 18 or older than 30
- Are currently taking chronic or acute medication (orthodox, homoeopathic, herbal or other) for any medical condition
- Use any recreational drugs and drugs of abuse
- Suffer or have a history of narcolepsy, obstructive sleep disorder (apnoea), mood disorders or circadian rhythm disorders (we will check this for you when we see you)
- Are currently suffering from any chronic or debilitating disease?
- Are a night shift workers or have travelled internationally within the last 6 weeks?
- Are commercial/occupational drivers, machine operators or pilots or have a history of sleep-associated incidents.
- Are pregnant

If you meet these criteria and want to participate we will book you an appointment at the Homoeopathic Day Clinic at DUT where you will meet us for the first consultation. The first consultation will take about 60 minutes to complete, we will ask you to provide written consent (permission) to participate after we have explained everything to you and given you time to ask any questions you may have.

Once this is done we will take detailed medical history (set of questions about your health history) and then do a basic physical examination which similar to what you would have done with your general practitioner. We will then fill in a questionnaire (ESS questionnaire) with you which tells us how sleepy you get during the day. After this you will be sent home with another questionnaire called a SSS which you will complete daily for 1 week, this also measures generally how alert you are during the day. One week later you will come back to the clinic and meet us again for 15 minutes only; at this point you will hand in the SSS which you have filled in and we will give you the medicine that we would like to test.

For the next two weeks you will take this medicine and continue filling in the SSS questionnaire on a daily basis. After two weeks of taking the medicine you will come back to the clinic for a 3rd time to meet us for 30 minutes where you will hand in the SSS questionnaires you filled in and we will fill in another ESS questionnaire. We will also do a final check and examination before you finish the study.

The medicine we are testing is a homoeopathic (natural medicine) which is used regularly in homoeopathic clinics, it is considered to be safe and there should be no side effects or dangers from taking this medicine, you will have to take the medicine for two weeks and we will supply you with enough medicine for this time. It is also important to note that 1/3 of participants i.e. 10 out of 30 will not get an active medicine, they will get a placebo (inactive medicine) this is necessary for use to test how well the active medicine works and is commonly done in medical research. You will only be told if you got the active medicine or the placebo at the end of the study

but if you were on the placebo we will offer you one free consultation and bottle of medicine at the end of the study.

Process	**How long**	**What will happen and where**
Telephone call (we will call you back)	5 minutes	With your permission we will ask you a set of questions to see if you qualify for the study over the phone
1st consultation	60 minutes	At the homoeopathic day clinic on Ritson Campus Case history (questions) Basic physical examination ESS questionnaire
2nd consultation (1 week later)	15 minutes	At the homoeopathic day clinic on Ritson Campus Hand in questionnaire Receive medicine Receive instructions
3rd consultation (2 weeks later)	30 minutes	At the homoeopathic day clinic on Ritson Campus Hand in questionnaires Case history (questions) Basic physical examination Referral if needed

Risks or Discomforts to the Participant:
Participating should not result in you experiencing any discomfort or any significant risks, we do not need to perform any painful procedures in this research.

Benefits:
If you receive the active medicine you may feel less sleepy and more alert during the daytime, if you were on the inactive placebo you will get 1course of free treatment for this at the end of the study for your daytime sleepiness. The researcher is doing this research to obtain her Master's degree in Homoeopathy from DUT.

Reason/s why the Participant May Be Withdrawn from the Study:
At any time during the study you can choose to withdraw/stop the study without having to provide a reason for leaving; further if you leave there will be no negative consequences for you. We may stop you participating in the study if you don't follow the instructions given or if you don't come for your appointments or if we feel you no longer meet the requirements for the study – if we do so we will refer you to the necessary doctor for further treatment if you need it.

Remuneration:
There will not be any payment for your participation in this study.

Costs of the Study:
Participating in the study will not cost you anything, i.e. you will not have to pay for the consultations or the medicines you receive while on this study.

Confidentiality:
We will protect your identity and personal information; your file will be safely locked away and will not be available to anyone except the researcher and her supervisor. When we write up the research we will not mention any names and everything you tell us in the consultations is confidential as it would be in any doctor's visit.

Research-related Injury:
It is highly unlikely that you will sustain any harm or injury from participating, however if you were to get sick or develop an allergy we will refer you to the necessary doctor who can take care of you.

Persons to Contact in the Event of Any Problems or Queries:

Research supervisor: Dr David Naude 0317652514 or 0823701012
Researcher: Nondumiso Shabangu 0761129187
Institutional Research Ethics administrator on 031 373 2900.
Complaints can be reported to the DVC: TIP, Prof F. Otieno on 031 373 2382 or dvctip@dut.ac.za.

Appendix B: Consent

CONSENT

Statement of Agreement to Participate in the Research Study:

- I hereby confirm that I have been informed by the researcher, _____ (name of researcher), about the nature, conduct, benefits and risks of this study - Research Ethics Clearance Number: _____,
- I have also received, read and understood the above written information (Participant Letter of Information) regarding the study.
- I am aware that the results of the study, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a study report.
- In view of the requirements of research, I agree that the data collected during this study can be processed in a computerised system by the researcher.
- I may, at any stage, without prejudice, withdraw my consent and participation in the study.
- I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.
- I understand that significant new findings developed during the course of this research which may relate to my participation will be made available to me.

Full Name of Participant Date Time Signature/Right Thumbprint

I, _____ (name of researcher) herewith confirm that the above participant has been fully informed about the nature, conduct and risks of the above study.

Full Name of Researcher Date Signature

Full Name of Witness (If applicable) Date Signature

Appendix C: Stanford Sleepiness Scale

The Stanford Sleepiness Scale is a quick and easy way to assess how alert you are feeling.

Discover your own pattern of alertness by recording your “degree of sleepiness” at different times throughout the day.

Using the 7-point scale below pick what best represents how you are feeling and note the corresponding number on the chart below:

Degree of Sleepiness	Scale Rating
Feeling active, vital, alert, or wide awake	1
Functioning at high levels, but not fully alert	2
Awake, but relaxed; responsive but not fully alert	3
Somewhat foggy, let down	4
Foggy; losing interest in remaining awake; slowed down	5
Sleepy, woozy, fighting sleep; prefer to lie down	6
No longer fighting sleep, sleep onset soon; having dreamlike thoughts	7
Asleep	X

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
7am							
8am							
9am							
10am							
11am							
12pm							

1pm							
2pm							
3pm							
4pm							
5pm							
6pm							
7pm							
8pm							
9pm							
10pm							
11pm							
12am							

What does this all mean?

Ideally, you would like a score of "1" for each of the hours you are awake. A result of 4 or below may indicate that you could be suffering from a lack of sleep. Getting a better night's rest could improve your level of alertness and day to day performance.

Use this tool to help schedule your classes during times you are most alert!

Appendix D: Epworth Sleepiness Scale

The Epworth Sleepiness Scale

0 = would **NEVER** doze
1 = **SLIGHT** chance of dozing
2 = **MODERATE** chance of dozing
3 = **HIGH** chance of dozing

SITUATION	CHANCE OF DOZING (0-3)
Sitting and reading	
Watching television	
Sitting inactive in a public place (e.g. a theater or meeting)	
As a passenger in a car for an hour without a break	
Lying down to rest in the afternoon when circumstances permit	
Sitting and talking to someone	
Sitting quietly after a lunch without alcohol	
In a car, while stopped for a few minutes in the traffic	
TOTAL SCORE	

SCORE RESULTS:

1-6 Congratulations, you are getting enough sleep!
7-8 Your score is average
9+ Very sleepy and should continue to seek sleep assistance.

Appendix E: Case taking form

DUT DURBAN UNIVERSITY OF TECHNOLOGY
FACULTY OF HEALTH SCIENCES
DEPARTMENT OF HOMOEOPATHY

Dr Corné Hall – HoD Homoeopathy
Reg no: A2868 ; Practice no: 0807036
11 Ritson Road, Berea, Durban, 4001
P.O.Box 1334 Durban, 4000
Tel : 031 3732041

HOMOEOPATHIC DAY CLINIC (D.U.T.) : CASE HISTORY

Appendix F: Soape note and treatment form

Dr Corné Hall – HoD Homoeopathy
Reg no: A2868 ; Practice no: 0807036
11 Ritson Road, Berea, Durban, 4001
P.O.Box 1334 Durban, 4000
Tel : 031 3732041

HOMOEOPATHIC DAY CLINIC (D.U.T.) : SOAPE NOTE & TREATMENT RECORD

Patient's Name & Surname:		**Date:**	
MAIN COMPLAINT(s)			
ON EXAMINATION			
Vital Signs:		**Height:**	**Weight:**
BP:		Observations(unusual)	
Temp:			
Pulse:			
Resp:			
DIAGNOSIS (Medical)	(the ICD code must match the written diagnosis)		
Written diagnosis:			
ICD-10 code:			
CENTER OF CASE (What needs to be addressed / changed)			
CASE ANALYSIS	(Grading: very common=1; common=2; slightly characteristic=3; very characteristic=4; PQRS=5)		

MENTAL	GENERAL	PARTICULAR

MIASM(S) (Active - motivate)			
CASE MANAGEMENT(Remedy differentials, posology and motivation and Patient management plan)			
Next Follow up appointment: (e.g. 3 weeks time)			
PATIENT EDUCATION(Advice)			
PRESCRIPTION			
POWDERS	**CREAM / TISSUE SALTS**	**VIALS**	**DROPS/∅**
Rx:	**Rx:**	**Rx:**	**Rx:**
Mitte:	**Mitte:**	**Mitte:**	**Mitte:**
Sig:	**Sig:**	**Sig:**	**Sig:**
Clinician's Auth:	**Clinician's Auth:**	**Clinician's Auth:**	**Clinician's Auth:**

SIGNATURES			
Clinicians Name:		**Students First Name:**	
Clinicians Signature:		**Students Signature:**	
Receptionist's signature:			
Name of dispenser:		**Date dispensed:**	

1

Appendix G: Research Quote

RESEARCH QUOTE

Date: 12 November 2014

Name of Student: Nondumiso Shabangu

Student number: 20909881

Summary of medicines/ consumables/ equipment to be used from the Homoeopathic Department for research purposes.

Item	**Quantity**	**Unit Price**	**Total**
Packets	45	R0.50	R22.50
Alcohol 20%	750ml	R 10/100ml	R75
TOTAL AMOUNT DUE			R 95.00

*This quote includes use of laboratory and laminar flow unit for the production of the research material.

QUOTATION FOR THE ITEMS MUST BE OBTAINED FROM THE TECHNICIAN PRIOR TO SUBMITTING RESEARCH BUDGET.

GOODS WILL BE DISPENSED AND INVOICED ON BUDGET AND ETHICS APPROVAL.

Appendix H: Letter of Permission to use the Homoeopathic day clinic

B 2559 Madadeni
Section 2
2951
19 January 2016

Dear Dr D.F Naude

Permission to use the Homoeopathic day clinic

I Nondumiso Shabangu currently registered for M. Tech qualification at Durban University of

Technology: Homoeopathy department. I am kindly requesting permission to use the Homoeopathic day clinic for consultation purpose for my research, as I am required to complete my partial dissertation by the end of 5th year (2016).

Research topic

The efficacy of a homoeopathic complex *(Nux moschata D6, Phosphoricum acidum D30,*

Helliborus niger D6, Opium D30) in the management of excessive daytime sleepiness

Purpose of the study

To determine and compare the efficacy of the *homoeopathic complex (Nux moschata D6, Phosphoricum acidum D30, Helliborus niger D6, Opium D30)* in the treatment of excessive daytime sleepiness with that of a homoeopathic simillimum and herbal complex using the Epworth Sleeping Scale and Stanford Sleeping Scale.

Please note that the clinician in charge or the supervisor will be present at all times to guide the consultations.

Your response to the above request will be appreciated.

Yours sincerely

Nondumiso Shabangu (20909881) Cell: 0761129187

Appendix I: Permission to use the Homoeopathic day clinic

B 2559 Madadeni

Section 2

2951

Cell: 0761129187

8 February 2016

Dear Drs

C. Hall (HOD)

C. Korporaal Clinic Director

S. Nienaber Clinic Co-ordinator

Re: Permission to use the Homoeopathic day clinic

I Nondumiso Shabangu currently registered for M. Tech qualification at Durban University of Technology:

Homoeopathy department am kindly requesting gatekeeper permission to use the Homoeopathic Day Clinic (HDC) for consulting with my research patients for the purpose for my research, as I am required to complete my partial dissertation by the end of 2016.

Research topic

The efficacy of a homoeopathic complex (Nux moschata D6, Phosphoricum acidum DO, Helliborus niger D6, Opium D30) in the management of excessive daytime sleepiness.

Purpose of the study

To determine the efficacy of the homoeopathic complex (Nux moschata D6,

Phosphoricum acidum D30, Helliborus niger D6, Opium D30) in the treatment of excessive daytime sleepiness using the Epworth Sleeping Scale and Stanford Sleeping Scale.

Methodology

I will be required to consult with 30 patients, each having three consultations at the HDC over a period of three weeks each. Clinical supervision will be provided by my Supervisor (Dr D. Naude) or a consenting Clinician on Duty, and I agree to follow all rules and policies relating to the HDC.

Yours sincerely

Nondumiso Shabangu (20909881)

Email: shabangunondu.sn@gmail.com

Appendix J: Permission to recruit DUT students

B 2559 Madadeni

Section 2

2951

Cell:0761129187

8 February 2016

Professor S. Moyo

Director of Research - DUT

Re: Permission to recruit DUT students for M. Tech: Homoeopathy research

I Nondumiso Shabangu currently registered for M. Tech qualification at Durban University of Technology: Homoeopathy department am kindly requesting permission to advertise and recruit DUT students to participate in my M. Tech: Homoeopathy research. This will be done by placing approved research posters on various notice boards as well as by word of mouth.

Research topic

The efficacy of a homoeopathic complex (Nux moschata D6, Phosphoricum acidum DO, Helliborus niger D6, Opium D30) in the management of excessive daytime sleepiness.

Purpose of the study

To determine the efficacy of the homoeopathic complex (Nux moschata D6, Phosphoricum acidum D30, Helliborus niger D6, Opium D30) using the Epworth Sleeping Scale and Stanford Sleeping Scale.

Methodology

I will be required to consult with 30 patients obtained by convenience sampling, each having three consultations at the DUT Homoeopathic Day Clinic over a period of three weeks each, Clinical supervision will be provided by my Supervisor (Dr D. Naude) or a consenting Clinician on Duty. The study is considered to be of

'minimum risk' to participants and approval has been sought from the Faculty of Health Sciences Research and Higher Degrees Committee and the IREC respectively.

Yours sincerely

Nondumiso Shabangu (20909881)
Email: shabangunondu.sn@gmail.com

Appendix K: Provisional Approval Letter IREC

Institution\ Research Ethics Committee
Faculty of Health Sciences
Room MS 49, Mansfield School Site Gate 8, Ritson Campus
Durban University of Technology

P O Box 1334, Durban, South Africa, 4001
Tel: 031 373 2900
Fax: 031 373 2407 Email: lavishad@dut.ac.za http://www.dut.ac.za/research/institutional research ethics www.dut.ac.za

25 July 2016

IRE-C Reference Number: REC 75116

Ms N Shabangu
House
2559
Section2
Madadeni 2951

Dear Ms Shabangu

The efficacy of a homoeopathic complex (Nux moschata D6, Phosphoricum acidum D30, Helliborus niger D6, Opium D30) in the management of excessive daytime sleepiness

I am pleased to inform you that Provisional Approval has been granted to your proposal REC 75/16 subject to:

- Obtaining and submitting the necessary gatekeeper permission/s to the IREC and
- Submission of proof of registration as a Clinical Trial

Full approval is subject to meeting the above conditions.

The Proposal has been allocated the following Ethical Clearance number IREC 06911 6. Please use this number in all communication with this office.

Approval has been granted for a period of two years, before the expiry of which you are required to apply for safety monitoring and annual recertification. Please use the

Safety Monitoring and Annual Recertification Report form which can be found in the Standard Operating Procedures [SOP's] of the IREC. This form must be submitted to the REC at least 3 months before the ethics approval for the study expires.

Any adverse events [serious or minor] which occur in connection with this study and/or which may alter its ethical consideration must be reported to the IREC according to the IREC SOP's.

Please note that any deviations from the approved proposal require the approval of the IREC as outlined in the IRE-C SOP's.

Yours

[redacted] Sincerely

Professor C E Napier

Chairperson: IREC (Acting)

Appendix L: Full Approval Letter IREC

Directorate for Research and Postgraduate Support
Durban University of Technology
Tromso Annexe, Steve Biko Campus
P.O. Box 1334, Durban 4000
Tel.: 031-3732576/7
Fax: 031-3732946 E-mail:
moyos@dut.ac.za

7th October 2016

Ms Nondumiso Shabangu c/o Department of Homoeopathy, Faculty of Health Sciences
Durban University of Technology

Dear Ms Shabangu

PERMISSION TO CONDUCT RESEARCH AT THE DUT

Your email correspondence in respect of the above refers. I am pleased to inform you that the Institutional Research Committee (IRC) has granted full permission for you to conduct your research "The efficacy of a homoeopathic complex *(Nux moschata D6, Phosphoricum acidum D30, Helliborus niger D6, Opium D30)* in the management of excessive daytime sleepiness" at the Durban University of Technology.

We would be grateful if a summary of your key research findings can be submitted to the IRC on completion of your studies.

Kindest regards.

Yours sincerely

[redacted]

PROF. S. MOYO DIRECTOR: RESEARCH AND POSTGRADUATE SUPPORT

Appendix M: Full Approval Letter Gatekeepers

Institutional Research Ethics Committee
Faculty of Health Sciences
Room MS 49, Mansfield School Site
Gate 8, Ritson Campus
Durban University of Technology
P O Box 1334, Durban, South Africa, 4001
Tel: 031 373 2900
Fax: 031 373 2407 Email: lavishad@dut.ac.za

I October 2016

IRE-C Reference Number: REC 75116

Ms N Shabangu House
2559

Section 2
Madadeni
2951

Dear Ms Shabangu

The efficacy of a homoeopathic complex (Nux moschata D6, Phosphoricum acidum D30, Helliborus niger D6, Opium D30) in the management of excessive daytime sleepiness

The Institutional Research Ethics Committee acknowledges receipt of your gatekeeper permission letter.

Please note that FULL APPROVAL is granted to your research proposal. You may proceed with data collection.

Yours Sincerely,

[redacted]

Professor I K Adam Professor J K Adam Chairperson: IREC

Appendix N: Repertorial analysis I

Repertorial analysis of EDS symptoms based on small remedies and rubrics

Small remedies + small rubrics - *Small remedies + small rubrics - Intensity is considered*

1	1234	1	SLEEP - SLEEPINESS - eating - after	107
2	1234	1	GENERALS - LASSITUDE - eating, after	21
3	1234	1	MIND - DULLNESS - eating, after	9
4	1234	1	MIND - PROSTRATION of mind - eating, after	3
5	1234	1	GENERALS - WEAKNESS - eating - after	63
6	1234	1	SLEEP - SLEEPINESS - overpowering	1 1 8
7	1234	1	SLEEP - FALLING ASLEEP - daytime	4

	lach.	**nat-m.**	**meph.**	**nux-m.**	**anac.**	**ant-c.**	**rhus-t.**	**bar-c.**	**ph-ac.**	**bar-act.**
	30	**27**	**27**	**25**	**24**	**24**	**23**	**23**	**21**	**21**
1	1	2	1	2	2	1	2	1	1	1
2	2	2	-	2	-	1	2	1	3	-
3	-	-	-	-	-	-	2	-	-	-
4	1	1	-	-	1	-	-	-	-	-
5	1	1	1	1	2	1	1	3	3	1
6	2	1	-	3	-	2	2	1	1	1
7	-	-	1	-	-	-	-	-	-	-

Appendix O: Repertorial analysis II

Repertorial analysis of EDS symptoms based on sum of symptoms and degrees

Sum of symptoms and degrees - *Sum of symptoms and degrees - Intensity is considered*

1	1234	1	SLEEP - SLEEPINESS - eating - after	107
2	1234	1	GENERALS - LASSITUDE - eating, after	21
3	1234	1	MIND - DULLNESS - eating, after	9
4	1234	1	MIND - PROSTRATION of mind - eating, after	3
5	1234	1	GENERALS - WEAKNESS - eating - after	63
6	1234	1	SLEEP - SLEEPINESS - overpowering	1 1 8
7	1234	1	SLEEP - FALLING ASLEEP - daytime	4

	rhus-t.	**lach.**	**nat-m.**	**nux-m.**	**ph-ac.**	**chin.**	**bar-c.**	**lyc.**	**ant-c.**	**ars.**
	14	**12**	**12**	**12**	**12**	**11**	**10**	**10**	**9**	**9**
1	2	1	2	2	1	2	1	2	1	1
2	2	2	2	2	3	1	1	2	1	-
3	2	-	-	-	-	-	-	-	-	-
4	-	1	1	-	-	-	-	-	-	-
5	1	1	1	1	3	2	3	1	1	3
6	2	2	1	3	1	2	1	1	2	2
7	-	-	-	-	-	-	-	-	-	-

Appendix P: Repertorial analysis III

Repertorial analysis of EDS symptoms based on prominence

Prominence - *Prominence - Intensity is considered*

1	1234	1	SLEEP - SLEEPINESS - eating - after	107
2	1234	1	GENERALS - LASSITUDE - eating, after	21
3	1234	1	MIND - DULLNESS - eating, after	9
4	1234	1	MIND - PROSTRATION of mind - eating, after	3
5	1234	1	GENERALS - WEAKNESS - eating - after	63
6	1234	1	SLEEP - SLEEPINESS - overpowering	1 1 8
7	1234	1	SLEEP - FALLING ASLEEP - daytime	4

	rhus-t.	**lach.**	**nat-m.**	**ph-ac.**	**nux-m.**	**chin.**	**lyc.**	**bar-c.**	**ant-c.**	**phos.**
	664	**544**	**544**	**540**	**484**	**460**	**444**	**440**	**419**	**419**
1	2	1	2	1	2	2	2	1	1	2
2	2	2	2	3	2	1	2	1	1	-
3	2	-	-	-	-	-	-	-	-	1
4	-	1	1	-	-	-	-	-	-	-
5	1	1	1	3	1	2	1	3	1	1
6	2	2	1	1	3	2	1	1	2	1
7	-	-	-	-	-	-	-	-	-	-

Appendix R: Manufacture of Complex

NONDUMISO SHABANGU HOMOEOPATHIC COMPLEX
BATCH NO: 117744
EXPIRY DATE: 08/2019

This formula was manufactured in accordance to the German Homoeopathic Pharmacopoeia which is laid out in a Standard Operating Procedure.

The following starting ingredients were measured out into equal parts (12.5ml each) and decanted into one amber glass bottle:

Nux moschata D5: 12.5ml
Acidum phosphoricum D29: 12.5ml
Helleborus niger D5: 12.5ml
Opium D29: 12.5ml

Vehicle used: 20% Ethyl alcohol 450ml

The above starting substances and alcohol were placed into an amber glass bottle. The liquid complex was succussed 10 times by hand.

The above step was performed once to get the ingredients to the desired potency.

Final product:
Nux moschata D6
Acidum phosphoricum D30
Helleborus niger D6
Opium D30
20% alcohol, 500ml