THE EFFICACY OF A HOMOEOPATHIC SIMILLIMUM IN THE MANAGEMENT OF EXCESSIVE DAYTIME SLEEPINESS

BY

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DECLARATION

I Ntombizethu Annie Mbatha, declare that this dissertation represents my own work, both in conception and execution

Signature of candidate **Date of signature**

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DEDICATION

Someone was passing the word of God in 2011 and read this scripture:

PROVERBS 3 vs 5

“Trust in the Lord with all your heart and lean not on your understanding”. This verse always lingers in my heart; as a result, it got me to this point of surpassing all glitches meant to prevent me from reaching this phase. Without you Father, I am nothing. I now know that in order for me to see you the distance is between my knees and the ground. THANK YOU.

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Khalathi Lydia Dlamini (Mother) and Bhekani Samson Mbatha (Father)

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ABSTRACT

Background

Sleepiness is a multifactorial phenomenon as it may possess 'trait' and 'state' features (Shahid, Shen and Shapiro, 2010). Trait features are influenced by individual personality and are long term while state features are short term (Shahid, Shen and Shapiro, 2010). Previous research reveals that excessive daytime sleepiness (EDS) affects approximately 10%-25% of the general population (Morrison and Riha, 2012) and can therefore have a negative impact on daily functions (Shahid, Shen and Shapiro, 2010). Moreover, Johns (1991) states that 50% of healthy medical students usually fall asleep during the day at least once in an average week, which could negatively affect academic performance. This research focuses on the management of EDS through utilising a homoeopathic simillimum approach to provide an important reference for practitioners regarding this troubling condition.

Aim The aim of this randomised, double-blind placebo-controlled study was to determine the efficacy of the homoeopathic simillimum in the management of EDS in terms of the Epworth Sleepiness Scale (ESS) (Johns, 1991) and the Stanford Sleepiness Scale (SSS) (Hoddes *et al*., 1973).

Methodology

By means of non-probability convenience sampling, the first 31 respondents to the published advertisement who met the inclusion criteria and provided informed consent were recruited. Participants were randomly divided into two groups; the active group (group 1) comprising 20 participants and the placebo group (group 2) comprising 11 participants.

Participants attended three consultations with the researcher and received their individually determined homoeopathic simillimum or a placebo at their first follow up appointment which was then administered over a treatment period of two weeks. Response to treatment was determined using two existing, validated, data collection tools namely, the Epworth Sleepiness Scale (Johns, 1991) and Stanford Sleepiness Scale (Hoddes et al., 1973). Quantitative data were subjected to general linear model

(GLM) repeated measures statistical techniques which were used to measure the effect of treatment at various time points both within subjects and between them.

Results

According to ESS both groups experienced an overall improvement in EDS symptoms. The active group experienced a higher reduction in mean ESS scores compared to the placebo (40% and 31% respectively) but this did not reach statistical significance ($p > 0.05$) despite the perceived improvement in the participants' sleepiness.

With respect SSS data, a repeated measures ANOVA method failed to show significant difference between placebo and active groups ($p > 0.05$).

Conclusion

Both the ESS and SSS data collection tools proved to be valuable in measuring the severity of EDS in tertiary students. Although EDS symptoms improved to a greater degree in those who received homoeopathic simillimum according to ESS data, this improvement was not statistically superior to placebo. SSS data however was comparable between groups throughout the study. *Natrum muriaticum* was the most prescribed remedy and thus, it can be a remedy to consider for EDS. A flexible potency selection as well as extended time frame for the study could provide a better evaluation of the efficacy of the homoeopathic simillimum treatment on EDS.

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DEFINITION OF TERMS

Aggravation: An increase in symptom severity in response to external stimuli, internal events such as changes in body functions or to the administration of medication or other therapeutic intervention (Swayne, 2000).

Centesimal scale: Where the dilution ratio is one-part medicinal substance to 99-parts water, with a certain number of succussions between each dilution (Olenev, 2014).

Cheyne-stokes breathing: A pattern of periodic gradual increase and/or decrease variation in tidal volume resulting in central apnoea and hypopnea occurring at a frequency of at least five events per hour accompanied by frequent arousals (Tortora and Derrickson, 2009).

Epworth sleepiness scale: A simple, reliable and valid method for assessing daytime sleepiness in adults. Participants are required to respond to items regarding perceived levels of sleepiness on a 4-point scale (Hayley *et al.*, 2014).

Excessive daytime sleepiness: Difficulty maintaining an alert awake state during the wake phase of the 24-hour sleep-wake cycle, characterised by an increased tendency to fall asleep when intending to remain awake (Hayley *et al.,* 2014).

Hahnemannian method of potentisation: The stepwise dilution of solid or liquid preparations according to the prescribed method (Driehsen, 2003).

Homoeopathy: The art and science developed by Dr Samuel Hahnemann which involves healing of the totality of symptoms in a disease by means of medicines that are capable of generating symptoms in healthy individuals that are similar to those of the disease itself (O'Reilly, 1996).

Infinitesimal dose: An idea that in much smaller doses the drug is required to bring about a reaction in the diseased body, as homeopathy is based on the paradigm of healing in which the patient brings about the cure after the remedy has stimulated the patient's curative powers (De Schepper, 2006).

Materia medica: A book that includes the individual homoeopathic remedies and their indications (Reichenberg-Ullman and Ullman, 2000).

Miasm: The societal, family or individual traits causing vulnerability towards a particular pattern or disease, which can be acquired or inherited. (Swayne, 2000:137)

Placebo: A substance that is pharmacologically inert, thus not having a physiological action (Chauhan and Gupta, 2007).

Potentization: It's the stepwise dilution of solid or liquid preparations according to the prescribed method (Driehsen, 2003).

Repertorisation: Coming from Latin *reperio, -ire, repperi, -tum* meaning "to find out". A repertory is reference book that schematically indexes the symptoms located in the materia medica. The symptoms are classified structurally relating to each appropriated medicine. It assists in the proper identification of the remedy (Gaier, 1991).

Simillimum: The single homoeopathic remedy chosen based on the correlation between its drug picture (clinical indications) and the total symptom complex presented by the patient. The selection of the simillimum is based on the biological law of similars *similia similibus curentur,* one of the fundamental laws of homeopathy (Gaier, 1991) i.e. the resemblance between toxic and the therapeutic actions of the same substance. This means that the symptoms displayed by the sick person are cured by the substance that is capable of producing the same symptoms in a healthy individual (Gaier, 1991).

ACRONYMS

EDS: Excessive Daytime Sleepiness

EEG: Electroencephalogram

ESS: Epworth Sleepiness Scale

REM: Rapid Eye Movement

CHAPTER 1: OVERVIEW

1.1 INTRODUCTION

Excessive daytime sleepiness (EDS) is a difficulty maintaining alertness during a 24-hour sleep-wake cycle (Kendzerska *et al*., 2014). According to Morrison and Riha (2012), persistent sleepiness is often associated with impaired alertness causing a significant negative impact on an individual's quality of life, adding to an impairment of performance and resulting in safety issues.

Daytime sleepiness is deemed to be a level of daytime sleepiness which interferes with daily activities, and is most prevalent in adolescents, older persons and shift workers, but affects an estimated 20 percent of the general population (Pagel, 2009). Furthermore, people who have EDS are at a higher risk of being involved in motor vehicle and work-related incidents and have poorer health when compared to other adults. Daytime sleepiness is the leading symptom of patients in the United States presenting to sleep clinics (Pagel, 2009).

Adolescents who suffer from EDS experience poor academic performance, increased 'tardiness' at school and lower graduation rates (Pagel, 2009). Pagel (2009) continues to say that better school performance is associated with more time in bed and better sleep quality. Sleep disturbance and daytime sleepiness were extremely common in the adolescent population at Colorado State University i.e. 45.7% and 54.6% respectively.

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

The current treatment for the EDS is mainly psychostimulant drugs such as amphetamine derivatives, methylphenidate and premoline (sympathomimetics) as well as non-sympathomimetics like caffeine and modafinil (Banerjee, Vitiello and Grunstein, 2004). These drugs contain a wide variety of side effects that include drug

toxicity, drug interaction, dependency and drug abuse (Banerjee, Vitiello and Grunstein, 2004).

In homeopathy, the curative power of the remedy is based on the symptom similarity of the potentised remedy that will create a stronger disorder than the natural disease (De Schepper, 2006). Homoeopathy seeks to individualise prescriptions according to the totality of symptoms (physical, mental and emotional) (Ullman, 1991). The core principle of homoeopathy is not to treat a disease but to treat a patient with a disease (De Schepper, 2006). The homoeopathic remedy itself strengthens the vital force by creating the artificial disease features to further stimulate the healing action of the organism (De Schepper, 2006). By increasing the strength of the vital force homoeopathy acknowledges the connection of the mind, emotions, body and spirit as it creates homeostasis in the organism (De Schepper, 2006).

1.2 CONTEXT OF RESEARCH

Occasional daytime sleepiness is common; those who regularly have restricted nocturnal sleep such as college students may suffer from EDS chronically. Given the negative consequences of this condition such as lower work productivity and general well-being, as well as increased risk of car accidents and interpersonal difficulty, further study of this condition is warranted (Breslau *et al.*, 1997).

Traditional orthodox pharmacotherapy for EDS includes psychostimulant drugs such as amphetamine derivatives, methylphenidate and premoline (sympathomimetics) as well as non-sympathomimetics like caffeine and modafinil. Such drugs are well associated with a wide variety of common side effects, toxicity, drug interactions, dependency and abuse (Banerjee, Vitiello and Grunstein, 2004). Further research on new pharmaceutical products which promote wakefulness in EDS safely and effectively are needed; the ideal product should promote wakefulness, without negatively influencing sleep and without the risk of dependence, withdrawal or rebound (Banerjee, Vitiello and Grunstein, 2004).

The homoeopathic simillimum is the single homoeopathic remedy chosen based on the correlation between its drug picture (clinical indications) and the total symptom complex presented by the patient. The selection of the simillimum is based on the biological law of similars, *similia similibus curentur,* one of the fundamental laws of

homoeopathy (Gaier, 1991). The prescription of the simillimum on an individualised basis is the hallmark of good homeopathic practice and it is this practice which is often termed *classical homeopathy* (Gaier, 1991).

The application of this individualised homoeopathic modality has been assessed in various clinical studies and has proved effective in the following conditions; chronic primary insomnia (Naudé, Couchman and Maharaj 2010) asthma in children (Shafei, AbdelDayem and Mohamed 2012) and chronic sinusitis (Nayak *et al.,* 2012). Further, a meta-analysis of 32 randomised controlled trials applying the individualised homeopathic approach confirmed that this method has demonstrated efficacy superior to that of placebo, including conditions such as headache, diarrhoea, rheumatoid arthritis, recurrent upper respiratory tract infection, premenstrual syndrome, post-viral fatigue syndrome, attention deficit syndrome (Linde and Melchart, 1998).

1.3 AIM OF THE STUDY

The aim of this randomised, double-blind placebo-controlled study was to determine the efficacy of the homoeopathic simillimum in the management of excessive daytime sleepiness in terms of the Epworth Sleepiness Scale (Johns, 1991) and Stanford Sleepiness Scale (Hoddes *et al*., 1973).

1.4 OBJECTIVES

Objective 1: To determine the efficacy of the homoeopathic simillimum in the management of excessive daytime sleepiness in terms of the Epworth Sleepiness Scale.

Objective 2: To determine the efficacy of in the homoeopathic simillimum the management of excessive daytime sleepiness in terms of the Stanford Sleepiness Scale.

1.5 HYPOTHESIS

It was hypothesised that the homoeopathic simillimum would be superior to placebo in the management of excessive daytime sleepiness in terms of the Epworth Sleepiness Scale and the Stanford Sleepiness Scale.

1.6 ASSUMPTIONS

- The participants' excessive daytime sleepiness condition was not caused by any underlying disorder or disease.
- Participants did not change their daily activities such as diets during the course of the study.
- Participants did not receive any treatment for EDS outside of this study.
- All patients adhered to the treatment regime.
- Participants completed their respective ESS and SSS honestly and accurately.

CHAPTER 2: REVIEW OF LITERATURE

2.1 SLEEP IN PERSPECTIVE

Sleep is an active process that requires energy and is a process that mammals require as it is a necessity. It is termed as a cyclically occurring state of reduced motor activity and perception when compared to when a person is awake or alert (Stanfield and Germann, 2007). Sleep functions as a restorative so that the body can fully recover from daily activities (Stanfield and Germann, 2007).

For one to remain awake from a sleep state, the Reticular Activating System (RAS) needs to be active due to nerve impulse transmission to different areas of the cerebral cortex via the thalamus. Thus, an awake state is known as a state of arousal or consciousness (Tortora and Derrickson, 2009). When one is asleep the RAS activity is low due to the inhibitory effect of adenosine (Tortora and Derrickson, 2009).

Table 2.1: Sleep stages

Sleep Stage	Brain Wave			First Appearance	Comments
	Defining EEG Frequency [cps]	Type	Characteristics		
Alert wakefulness	Fast, with many waves >13 cps	Beta	Low voltage, random pattern, with few rhythmic components		
Relaxed wakefulness	8-13 cps	Alpha	Low voltage, rhythmic alpha, with occasional bursts of the alertness pattern	The person is relaxed or drowsy, with eyes closed.	
NREM N1	3-7 cps	Theta	Theta waves Interspersed with brief periods of alpha waves	As soon as alpha waves are < 50% of a 30-second epoch	Reactivity to outside stimuli diminishes; sleepers may still feel awake
NREM N2	12-14 lasting >0.5 seconds. Isolated slow / high amplitude Waves	Theta with sleep spindles and K-complexes	At least 1 sleep spindle or K-complex per 30 seconds on a N1 back-ground	When the first sleep spindle or K-complex appears	The most prominent sleep stage, deeper than N1 sleep, lighter than SWS
NREM N3 – Slow Wave Sleep (SWS)	< 4 cps	Delta	High amplitude, low waves	Usually occurs within 15-45 minutes after sleep onset	Deepest sleep; duration of SWS depends on age (less in the elderly)
REM sleep	N1 pattern with “saw tooth waves”	Low voltage, random, fast	Eyes move; the autonomic system is activated (e.g., respiratory and cardiac irregularities).	First REM period occurs after ~85 minutes of NREM sleep.	A unique state, in which dreams usually occur. The brain is awake & body paralysed (REM-related atonia).

Source: Hauri (2011)

There are two states of sleep, each state distinguished by the presence of absence of eye movement called non-rapid eye movement (NREM) which is comprised of four phases, and rapid eye movement (REM) (Widmaier, Raff and Strang, 2008; Doghramji, 2011).

NREM is the first state of sleep and accounts for 75%-80% of total sleep time. It comprises four stages with increasing depths of sleep. Slow rolling eye movements occur initially (phase 1) which disappear as subsequent stages are reached. Similarly, muscle activity decreases from stage one to four, with stage three and four referred to as 'deep sleep' or 'high quality' sleep (Doghramji, 2011). NREM sleep is characterised by a unique electroencephalogram (EEG) pattern. During the first stage of NREM sleep theta waves begin to be scattered amongst the alpha pattern. In the second stage the sleep spindles burst due to high frequency and K complexes as they have high amplitude and occasionally disrupt the theta wave (Widmaier, Raff and Strang, 2008). In the third stage of NREM sleep, there is an appearance of delta waves along with the theta rhythm and in fourth stage there's a dominant pattern of the delta rhythm (Widmaier, Raff and Strang, 2008). The progression of sleep takes about thirty to forty-five minutes and includes all four stages of NREM sleep. The process will then reverse itself as the EEG resumes a low amplitude, high amplitude, asynchronous pattern that appears to be similar to the alert-awake state, but the behavioural patterns of sleep continue with REM sleep instead of reversing to the wake state (Widmaier, Raff and Strang, 2008).

First Stage of NREM sleep (Chieh, 2015):

Stage 1 occurs once a person decides to sleep and the eyes initially close. This stage lasts for one to ten minutes and during this stage the patient is lightly asleep and can vigorously return to a fully awake state.

Features:

1. Although the person may feel asleep, they may wake up feeling as if he/she never went into a sleep state.
2. The body's muscles are not yet inhibited, the eyes still move slightly and the person may slightly open their eyelids.
3. Depreciation of breathing rate and heart rate becomes regular.
4. Reduction in blood pressure and body temperature.
5. Hypnic jerk (twitching of body parts when falling asleep).

Second Stage of NREM sleep (Chieh, 2015):

This stage lasts for about twenty minutes.

Features:

1. Slowing of heart rate.
2. Decrease in body temperature.
3. Difficulty waking up.
4. Brain begins to emit larger waves.
5. Reduction of blood pressure and slowing down of metabolic functions.

Third and Fourth Stage NREM sleep (Chieh, 2015):

The third stage occurs about thirty-five to forty-five minutes after sleep onset.

Features:

1. The EEG shows brain waves slowing down and becoming larger.
2. A person can sleep without showing any reaction in the presence of external factors e.g. noise, which may awaken a person.

REM sleep which follows each cycle of NREM sleep is also known as paradoxical sleep as the sleeper is difficult to arouse despite an EEG characteristic of the alert, awake state (Widmaier, Raff and Strang, 2008). Oxygen consumption during REM is higher when compared with NREM. When a person is awakened during REM sleep generally he/she reports that they were dreaming. If uninterrupted, a cyclical fashion of sleep occurs resulting in movement from NREM stages one, two and three to four and then back up from four to three, to two, and then to an episode of REM sleep (Widmaier, Raff and Strang, 2008). The number of the above-mentioned cycles in adults happen four to five times a night (Widmaier, Raff and Strang, 2008). The first episode of REM lasts ten to twenty minutes, and is followed by another NREM pattern. These two states alternate throughout the night (Tortora and Derrickson, 2009).

REM features (Chieh, 2015):

1. Eyes are locomotive to all directions.
2. During first stage of sleep, sleep is in its deepest form, therefore there is a presence of powerful dreams. Sleep walking and bedwetting episodes usually occur in this state.
3. Increase in heart and respiration rates, rhythms may become irregular.
4. REM stages gets longer and longer as night goes by and the last REM may last an hour.

2.2 INTERNATIONAL CLASSIFICATION OF SLEEP DISORDERS

The international classification of sleep disorders is made according to the Diagnostic and Statistical Manual of Mental Disorders (5th Edition) (American Psychiatric Association, 2015), commonly known as DSM-5.

2.2.1 Insomnia disorder

According to the DSM-5 (American Psychiatric Association, 2015) insomnia disorder is known as the feeling of dissatisfaction of quality and quantity of sleep with the challenge of initiating or maintaining it. This disorder, with a diagnostic code of 780.52, may cause disruption in social, occupational or other areas of functioning. Insomnia may be differentiated into sleep-onset insomnia, where there is difficulty initiating sleep, or sleep maintenance insomnia which involves frequent awakenings throughout the night, or late insomnia which involves early-morning awakening with difficulty going back to sleep.

2.2.2 Hypersomnolence disorder

Hypersomnolence disorder is a broad term describing an excessive quantity of sleep with a reduced quality of wakefulness. Sleep efficiency is good. People affected with the condition have a tendency to fall asleep easily. Waking up in the morning becomes a challenge, with an appearance of confusion, combative, or ataxia. Chronic forms of the condition result in sleep inertia (sleep drunkenness). Individuals may appear awake but experience deterioration in physical activities, memory deficiency, inappropriate behaviour and are disoriented in time and space. These symptoms may

last from minutes to hours. Prevalence is approximately 5%-10% in the general population and relatively equal in both males and females.

2.2.3 Narcolepsy

Narcolepsy is a condition where an individual experiences recurrent daytime naps or lapses into sleep. Typically, sleepiness occurs daily but must occur three times a week for three months. Narcolepsy is normally accompanied by cataplexy. Nevertheless, the individual remains aware and awake when the state of cataplexy occurs. Narcolepsy affects 0.02%-0.04% of the general population affecting both males and females. Onset of this condition is in the periods 15-25 years and 30-35 years and is associated with an increased body mass index.

2.2.4 Breathing-related sleep disorders

According to the DSM-5 (American Psychiatric Association, 2015) breathing related disorders are the repeated episodes of upper airway obstruction. This is the most common disorder associated with a reduction in oxygen saturation from 3% and/or above. The diagnosis is based on nocturnal breathing disturbances, daytime sleepiness, and evidence by polysomnography of five or more obstructive apnoeas or hypopneas in one night. Prevalence is between 2%-15% in middle aged adults, more than 20% in older adults and 2% in children.

2.2.5 Central sleep apnoea

Central sleep apnoea involves apnoea or hypopnea during sleep with aetiology of variability in respiratory events that occur in a periodic or intermittent pattern. Individuals with heart failure, stroke or renal failure are mostly affected by this disorder. Typically, a breathing pattern experienced by the individuals is known as Cheyne-Stokes breathing and increases with age. Another aetiological factor can be long term usage of opioid medications. Symptoms experienced are sleepiness, confusion, and depression.

2.2.6 Sleep-related hypoventilation

Sleep-related hypoventilation is a slowly progressive disorder of respiratory impairment that occurs repeatedly with other disorders such as chronic obstructive

pulmonary disease, neuromuscular disorder, and obesity. Complications are pulmonary hypertension, cor pulmonale, cardiac dysrhythmias, polycythemia and neurocognitive dysfunction. The symptoms are excessive sleepiness or insomnia, headache upon awakening, and shallow breathing.

2.2.7 Circadian rhythm sleep-wake disorders

According to the DSM-5 (American Psychiatric Association, 2015), there are five types of circadian rhythm sleep-wake disorders, namely, delayed sleep phase type, advanced sleep phase type, irregular sleep-wake type, non-24-hour sleep-wake type and the shift work type.

- **Delayed sleep phase type:** There is a history of delay in timing of major sleep periods in relation to the desired sleep and wake up time, resulting in sleep onset insomnia with difficulty waking up in the morning and early day excessive sleepiness.

- **Advanced sleep phase type:** This is generally familial. The sleep wake times of this type are several hours earlier than the desired or conventional times. The disorder is reliant on history of advancement in the timing of the major sleep period which is usually more than two hours in relation to the sleep and wake up time. The signs and symptoms are early morning insomnia and excessive daytime sleepiness.
- **Irregular sleep-wake type:** Characterised by a lack of discernible sleep-wake circadian rhythm. There is no major sleep period. Sleep is fragmented into at least 3 periods during the 24-hour day. Longest sleep period is between 02:00am and 06:00am. Signs and symptoms are insomnia at night and excessive daytime sleepiness.
- **Non-24-hour sleep-wake type:** Abnormal synchronisation between 24-hour light-dark cycle and endogenous circadian rhythm. Symptoms are insomnia and excessive daytime sleepiness.
- **Shift work type:** This is characterised by working outside the normal daylight working hours of 08:00am to 18:00pm. The individual experiences excessive sleepiness at work and impaired sleep at home.

2.2.8 Parasomnias

Parasomnias are disorders characterised by abnormal, behavioural, experiential, or physiological events occurring in association with sleep, specific sleep stages, or sleep wake transitions (American Psychiatric Association, 2015).

- **Non-rapid eye movement sleep arousal disorder:** Regarded as the repeated occurrence of incomplete arousals, usually starting during the first third of the major sleep episode, lasting one to ten minutes, but may be protracted lasting up to one hour. Interestingly, the eyes are open during these events. It is characterised by sleep walking (code 307.47) elaborated as repeated episodes of complex motor behaviour initiated during sleep, or sleep terrors defined as repeated occurrence of precipitous awakenings beginning with a panicky scream followed by intense fear. After the episode the individual experiences difficulty waking up.
- **Rapid eye movement sleep behaviour:** This is the repeated episode of arousal associated with vocalisations and/or complex motor behaviours arising from REM sleep characterised by action-filled or violent dreams of being attacked or trying to escape from a threatening situation termed dream enacting behaviour. Upon awakening, the individual is fully alert and is often able to recall a dream.

2.2.9 Restless leg syndrome

Restless leg syndrome is a sensorimotor, neurological sleep disorder with a desire to move legs or arms in conjunction with uncomfortable sensations such as creeping, crawling, tingling, burning or itching. Symptoms of an individual are elevated when at rest especially in the evenings or at night and onset of sleep may be delayed, or the individual can be awakened from sleep. Restless leg syndrome is associated with daytime sleepiness.

2.2.10 Substance / medication-induced sleep disorder

A prominent sleep disorder that is sufficiently severe to warrant independent clinical attention. It is associated with drug use, medication and toxic exposure. Impairment in social, occupational or other important areas of functioning may be detected.

2.3 EXCESSIVE DAYTIME SLEEPINESS (EDS)

Excessive 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 (Kendzerska *et al*., 2014).

The most used operational definition of sleepiness is the speed, ease or likelihood of falling asleep as opposed to remaining awake and is represented by instantaneous sleep propensity, situational sleep propensity and average sleep propensity (Kendzerska *et al*., 2014). According to Morrison and Riha (2012), persistent sleepiness is often associated with impaired alertness causing a significant negative impact on an individual's quality of life, adding to an impairment of performance and resulting in safety issues. EDS as a manifestation of disturbed sleep or sleep deprivation has tremendous consequences that affect individuals and society in general (Fatani *et al.*, 2015).

Sleepy people often explain how they doze off inadvertently while engaged in activities that involve low levels of stimulation, relative immobility and relaxation such as watching television and sitting (Johns, 1991). Individuals with this disorder may complain of excessive sleepiness which may result in the impairment of social, occupational, or other important areas of functioning (American Psychiatric Association, 2015). Most individuals do not seek intervention as their symptoms are not severe. With people who are called back for evaluation, it is often due to the condition being more persistent and troubling to them. The diagnosis rests mainly on the clinical history, pattern of work, sleep, naps, and free time (American Psychiatric Association, 2015).

2.3.1 SIGNS AND SYMPTOMS

Excessive daytime sleepiness compromises quality of life as it causes impairment in work performance, interpersonal relations, and cognitive and neuropsychological function, and can result in motor vehicle accidents, metabolic and cardiovascular diseases (Bediwy *et al*., 2015). According to the National Sleep Foundation (2017), although EDS is not a disease, its persistence may be an indication of an underlying medical condition such as obstructive sleep apnoea. The signs and symptoms of this condition include lack of concentration, extreme tiredness, lack of engagement with

strenuous activities and an inability to remain alert even when they were previously alert (Pagel, 2009).

2.3.2 INCIDENCE AND PREVALENCE

Prevalence of EDS is found to be higher in women than in men but more during middle age (50-59 years) and above 80 years of age (Hayley *et al*., 2014). 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 older females were twice more likely to have EDS compared with young males due to their short hours of sleep per night (Fatani *et al.,* 2015). However, the prevalence of EDS for males and females was similar within middle-aged (ages 30-59 years) and the elderly groups (ages above 70 years) (Fatani *et al*., 2015).

It is evident that daytime sleepiness is highest amongst adolescents, older persons and shift workers (Pagel, 2009). People who have EDS are at a higher risk of being involved in motor vehicle and work-related incidents and have poorer health when compared to adults. About 20% of adults in the United States report a level of daytime sleepiness which interferes with daily activities, and daytime sleepiness is the leading symptom of patients presenting to sleep clinics (Pagel, 2009).

The incidence of EDS amongst college students has been shown to be relatively high:

- Taiwanese 27% (Tran *et al.*, 2013)
- Peru 35% (Wittier *et al*., 2013)
- Chile 28% (Concepcion *et al*., 2013)
- Ethiopia 26% (Robinson *et al*., 2013)
- USA (Colorado) 54.6% (Pagel, Forister and Kwiatkowsi, 2007)

Adolescents who suffer from EDS experience poor academic performance, increased ‘tardiness’ at school and lower graduation rates (Pagel, Forister and Kwiatkowsi, 2007). According to Meng-Ting (2013), EDS is highly associated with emotional disturbances; therefore, there should be regular assessments of the emotional disturbances and health perception in college students. Pagel, Forister and Kwiatkowsi (2007) states that better school performance is associated with more time in bed and better sleep quality. Furthermore, sleep disturbance and daytime sleepiness were extremely common in the adolescent population at Colorado State

University i.e. 45.7% and 54.6% respectively. It was also found that about 50% of ostensibly healthy medical students usually sleep during the day at least once in an average week (Pagel, Forister and Kwiatkowsi, 2007).

2.3.3 AETIOLOGY

According to Banerjee, Vitiello and Grunstein (2004), there are many causes of EDS including:

1. Intrinsic sleep disorders such as narcolepsy, obstructive sleep apnoea/hypopnoea syndrome, and idiopathic hypersomnia.
2. Extrinsic sleep disorders e.g. inadequate sleep hygiene, insufficient sleep syndrome, toxin induced sleep disorder.
3. Circadian rhythm sleep disorders e.g. delayed sleep phase disorder, time-zone change (jet lag) syndrome, and shift work sleep disorders.
4. Sleep disorders associated with mental disorders e.g. psychosis, mood disorders, anxiety disorder.

Hayley *et al*. (2014) mention that alcohol use has been recognised as an additional contributing factor in EDS due to the disturbance of sleep architecture. The authors further state that the immediate impact of EDS can be debilitating, and in some cases can life threatening; as a result, it is a contributing factor towards poor occupational and social functioning.

2.4 TREATMENT

2.4.1 ORTHODOX (ALLOPATHIC) TREATMENT

Traditional orthodox pharmacotherapy for EDS includes psychostimulant drugs such as amphetamine derivatives, methylphenidate and premoline (sympathomimetics) as well as non-sympathomimetics like caffeine and modafinil. Such drugs are associated with a wide variety of common side effects, toxicity, drug interactions, dependency and abuse. Further research on new pharmaceutical products which promote wakefulness in EDS safely and effectively are needed (Banerjee, Vitiello and Grunstein, 2004). The ideal product should promote wakefulness without negatively impacting on sleep and without the risk of dependence, withdrawal or rebound (Banerjee, Vitiello and Grunstein, 2004).

Treating the underlying cause of EDS remains the mainstay of the therapy but for those that continue to sleep excessively, further administration of treatment may be warranted (Banerjee, Vitiello and Grunstein, 2004)

2.4.1.1 Sympathomimetics

Sympathomimetics are drugs that resemble the action of the sympathetic nervous system (Dreyer *et al*., 2012). Sympathomimetics directly act on the alpha and/or beta adrenergic receptors, and can therefore mimic the action of the endogenous agonist noradrenaline, or they will act indirectly on the nerve terminals thus increasing the release of noradrenaline and prevent the re-uptake of noradrenaline (Dreyer *et al.,* 2012). Typical examples of sympathomimetics are amphetamines, methylphenidate, and premoline. The side effects mostly seen are vasoconstriction and a rise in blood pressure (Dreyer *et al.,* 2012).

Amphetamines drugs are known to be more efficient and currently are the second most prescribed stimulant for narcolepsy in the United States after methylphenidate (Banerjee, Vitiello and Grunstein, 2014). This drug initiates the release of noradrenaline from the peripheral nerve terminals resulting in enhanced sympathetic activity thus causing side effects that may be intolerable.

Methylphenidate (methylα-phenyl-2-piperidineacetate), which is the leading psychostimulant prescribed in the United States, is said to be more potent as it has a half-life of six hours and is taken when needed (Banerjee, Vitiello and Grunstein, 2004). It is metabolised rapidly and therefore excreted in urine primarily as the inactive metabolite ritalinic acid which accounts for 80% of the dose. Allopathically, it has a better therapeutic index meaning the adverse effects are less when taken in doses that provide a therapeutic benefit (Banerjee, Vitiello and Grunstein, 2004).

Banerjee, Vitiello and Grunstein, (2004) state that premoline is a milder stimulant when compared to amphetamines but has a high liver toxicity and is thus not commonly used.

The abuse liability of sympathomimetic drugs has received considerable attention; even in low doses they have a tendency to produce affective states, characterised by intensified feelings of contentment, relaxation and euphoria (Banerjee, Vitiello and

Grunstein, 2004). This has given rise to clinicians being wary of the risks of dependency and abuse (Banerjee, Vitiello and Grunstein, 2004).

2.4.1.2 Non-sympathomimetics

Examples of the non-sympathomimetics are caffeine and modanifil. As explained by Banerjee, Vitiello and Grunstein (2004), modanifil (also known as 2-phenyl methylsulfinylacetamide) contains wakefulness-promoting properties and is a popular alternative to psychostimulants. It is therefore the first line agent for the treatment of excessive daytime sleepiness (Pagel, 2009). The advantage of using modanifil is it induces wakefulness in the absence of other properties which may cause autonomic arousal (Dreyer *et al*., 2012). The absorption of modanifil is rapid, its bioavailability is not affected by food, and it is well distributed within body tissue (Banerjee, Vitiello and Grunstein, 2004). The main route of elimination is metabolism primarily by the liver and excreted through urination. Therefore if the patient has hepatic impairment, modanifil should be administered at lower doses (Banerjee, Vitiello and Grunstein, 2004). The co-administration of modanifil with diazepam, phenytoin, and propranolol may increase levels of these drugs.

Caffeine is a natural alkaloid which is rapidly absorbed through the gastrointestinal tract and therefore reaches plasma levels between thirty and seventy-five minutes after administration (Banerjee, Vitiello and Grunstein, 2004). The half-life of caffeine varies between three and seven hours dependant on numerous factors such as pregnancy, smoking, age, gender and oral contraceptive usage (the latter increases half-life) (Banerjee, Vitiello and Grunstein, 2004).

2.5 HOMEOPATHIC TREATMENT

2.5.1 Fundamental principles of homeopathy

Homeopathy is the art and science developed by Dr Samuel Hahnemann, constructed from healing the totality of symptoms in a disease by means of medicines that are capable of generating symptoms in healthy individuals, similar to those of the disease itself (O'Reilly, 1996). In homeopathy, when treating an individual, the cure must be rapid, gentle and permanent as the homeopath's calling is to make the sick healthy (De Schepper, 2006). The energy required to keep the individual in a homeostatic

state is known as the vital force (De Schepper, 2006). A material organism without the vital force becomes inactive, non-sensible and lacks self-preservation therefore it is essential to have a life force such as this one. Furthermore, in homeopathy there are laws and principles which include observation of the totality of symptoms, finding the homeopathic similimum, the use of a single remedy, the infinitesimal dose, and Hering's law of cure (De Schepper, 2006).

The remedy must have characteristic features in accordance with the homeopathic features (De Schepper, 2006). It is imperative for the practitioner to obtain the totality of the symptoms (mental, emotional and physical symptoms). De Schepper (2006) further states that the remedy must be a single dose and should not be a substantial material dose.

2.5.2 Totality of symptoms

The totality of symptoms is a collection of symptoms that are present in an individual arising from one basic disturbance, which is the disease of the individual (Sankaran, 2009). Signs and symptoms existing together without being the cause of another are known as concomitant symptoms. When a thorough case has been taken by a homeopath, the concomitants become meaningful and form a clear picture of a disease (Sankaran, 2009).

The description of the case includes the pace of the disease, sensitivity of the disease, state of mind of the patient, nature of pathology and its meaning to the patient, aetiology, characteristic symptoms, the miasmatic consideration and history (Sankaran, 2009). In short, it takes into account the physical, mental and emotional states of the patient (De Schepper, 2006).

2.5.3 Homoeopathic simillimum

The homoeopathic simillimum is the single homeopathic remedy chosen based on the correlation between its drug picture (clinical indications) and the total symptom complex presented by the patient. The selection of the simillimum is based on the biological law of similars *similia similibus curentuur*, one of the fundamental laws of homoeopathy (Gaier, 1991). The prescription of the similimum on an individualised

basis is the hallmark of good homoeopathic practice and it is this practice which is often termed classical homoeopathy (Gaier, 1991).

Homoeopathic philosophy suggests that a disease is cured by introducing a minimal dose of a substance into the body that, in larger doses may induce symptoms similar to the disease in a healthy person ('like cures like') (De Schepper 2006). This principle, namely, the principle of similars, the principle of infinitesimal dose and the principle of the specificity of the individual were introduced by Hahnemann (De Schepper, 2006).

Finding the simillimum depends solely on the evaluation of symptoms; the cure must be rapid, gentle and effective (De Schepper, 2006). When the case is taken, the patient's symptoms become a living portrait of the symptoms of the indicated remedy. Thus, the information obtained is the etiologic diagnosis, where one determines the true cause of the condition. Secondly, it is necessary to discern the chronic miasmatic diagnosis (past and medical history) in order to determine the active miasm. Thirdly, there is a personality diagnosis (patient's constitution and temperament) which assists in determining the dosage (De Schepper, 2006). Lastly, there is the therapeutic diagnosis which is the determination of the current remedy as well as the timeline anticipated for each remedy (De Schepper, 2006).

The application of the individualised homeopathic modality has been assessed in various clinical studies and has proved effective in the following conditions:

- Chronic primary insomnia (Naudé, Couchman and Maharaj, 2010).
- Asthma in children (Shafei *et al*., 2012), with relative improvements after six months of homoeopathic treatment.
- Chronic sinusitis (Nayak *et al.,* 2012). The primary objective of this study was to ascertain the usefulness of homoeopathic medicine in the management of chronic sinusitis. The secondary objective was to assess the effect of homoeopathic medicines on changes in radiological appearance of chronic sinusitis. According to Nayak *et al*. (2012), the end result showed a significant reduction of the individual symptoms.

A meta-analysis of randomised placebo-controlled trials of individualised treatment revealed a statistically significant treatment effect of the individualised homoeopathic treatment based on reliable evidence (Mathie *et al*., 2014).

A meta-analysis of 32 randomised controlled trials applying the individualised homoeopathic approach confirmed that this method has demonstrated efficacy superior to that of placebo, including conditions such as headache, diarrhoea, rheumatoid arthritis, recurrent upper respiratory tract infection, premenstrual syndrome, post-viral fatigue syndrome, attention deficit syndrome (Linde and Melchart 1998).

2.5.4 Potency selection

According to Wieland (1997), the initial provings Hahnemann conducted were based on raw substances, but later he preferred 30CH for both provings and clinical usage.

Aphorism 128 of The Organon states:

“The provings done with substances in their raw state do not manifest nearly the full wealth of their hidden powers as they do in proving using substances in the potentised form... Therefore, even the substances deemed weak with regard to their medicinal powers are best investigated by having the prover take, on an empty stomach, with the 30CH potency of a certain substance, moistened, with little water, or rather dissolved in larger or smaller amount of water and well succussed. This should continue for several days.”

The above statement reveals the action of a 30CH potency at a physical, mental and emotional spheres as used in a proving; in clinical studies it shows a higher herapeutic effect (Wieland, 1997). This is therefore the reason the 30CH potency was chosen in this study.

2.5.5 The vital force

The vital force is referred to as the energy force within the body. It serves to maintain harmony in the body and without the vital force the body would remain inert (De Schepper, 2006). A homeopathic remedy strengthens the vital force so as to eliminate the disease from the body by creating a shadow of the disease to further stimulate the healing action of the vital force (De Schepper, 2006).

2.5.6 The infinitesimal dose

The principle of minimum dose describes a highly diluted substance in in which there are almost no molecules found; this prevents adverse reactions from occurring after administration of the remedy (De Schepper, 2006). This principle is similar to that of the Arndt-Schultz law of biochemistry which states that if the drug contains a minimum dose it will stimulate cellular activity, if the dose is medium it will inhibit or depress it, but if the dose is high it will destroy the cellular activity (De Schepper, 2006). De Schepper (2006) further states that the remedies are not active if they are only diluted but must be energised by succussion or trituration.

2.5.7 Hering's law of cure

- Healing occurs from interior to the exterior.
- Symptoms heal from the more vital organs to the least vital organs.
- Symptoms move from above to below, in reverse order of appearance (De Schepper, 2006).

CHAPTER 3: MATERIALS AND METHODS

3.1 SAMPLE SIZE

Since no sample frame exists for the research population in question, the researcher made use of non-probability sampling methods in the form of convenience sampling whereby the first 30 respondents to the published advertisement (Appendix A) who met the inclusion criteria (described in section 3.2) and provided informed consent (Appendix B) were recruited.

3.2 SELECTION CRITERIA

3.2.1 Inclusion criteria

Participants selected to partake in the study were required to meet the following criteria:

- Be between 18 and 30 years of age.
- Be a registered tertiary education student.
- Be willing to follow the research process including three consultations with the researcher as well as comply with the research protocol and provide written informed consent.
- Be in a general good state of health.
- Not be recovering alcoholics or religiously sensitive to alcohol.
- Have an ESS score of greater or equal to 10 (which suggests excessive sleepiness) (Johns, 1991; Morrison and Riha, 2012; Hayley *et al*., 2014) originating from inadequate sleep hygiene and/or insufficient sleep syndrome (Banerjee, Vitiello and Grunstein, 2004; Hayley *et al*., 2014).

3.2.2 Exclusion criteria

Subjects were excluded if they:

- Were younger than 18 or older than 30.
- Were currently taking chronic or acute medication (orthodox, homoeopathic, herbal or other) for any medical condition.

- Made use of any recreational drugs and drugs of abuse.
- They suffered or had a history of narcolepsy, obstructive sleep disorder (apnoea), mood disorders or circadian rhythm disorders.
- Were currently suffering from any chronic or debilitating disease.
- Were recovering alcoholics or religiously sensitive to alcohol.
- Worked night shift work or had travelled internationally within the last 6 weeks.
- Were commercial/occupational drivers, machine operators or pilots or had a history of sleep-associated incidents (Pagel, 2009).

3.3 RANDOMISATION

The supervisor conducted the randomisation of this study. This was done in a double-blind manner to ensure that neither the researcher nor the participant would know which group the participant was assigned to. The list was accessed by the researcher following completion of the trial. Each number was randomly allocated for either placebo or active group. Each new participant entered into the trial was assigned in a numerical order, which was a unique participant number for correlation to a number on the randomisation sheet to dispense accordingly. Dispensing of medication was performed by the laboratory technician at the Department of Homoeopathy, Durban University of Technology (DUT) Homoeopathic Day Clinic.

3.4 INTERVENTION

All remedies were prepared according to method 5a of the German Homoeopathic Pharmacopoiea (GHP) (Driehsen, 2003) at the Homoeopathic Day Clinic within the premises of the DUT. The intervention received by the placebo group was indistinguishable from the intervention received by the active group. The simillimum was dispensed in a 30 plussed potency (Appendix J) on the first follow up consultation and was dispensed only once throughout the trial. In the 6th edition of The Organon, Hahnemann emphasised the homoeopathic remedy with the rapid, gentle and permanent restoration of health. Thus, the use of this method was advised (Murphy, 2006).

- All participants received a 25ml dropper bottle with 20 ml homeopathic simillimum or placebo. The active remedy was made up according to method

5a of GHP: 10 medicated lactose granules of the chosen remedy was placed in the bottle, then 18 ml of distilled water was added to the bottle. The bottle was swirled until all granules had completely dissolved after which 2ml of 96% pure ethanol was added to the mixture. The bottle was securely closed then succussed 10 times. The quantity of the remedy was sufficient for 14 days. The participants were to administer 10 drops of the remedy 3 times a day, succussing it 10 times prior to each dose. The placebo was made up with 18 ml of distilled water plus 2ml of 96% pure ethanol. All the remedies were dispensed with a standardised label, each with a unique number corresponding to the randomisation number as stated in section 3.3.

Ethanol:

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

3.5 ETHICAL CONSIDERATIONS

This study met the requirements laid out in the Declaration of Helsinki (WMA, 2013) and was methodologically compliant with the South African Department of Health Ethics in Health Research Guidelines (Department of Health, 2004). Ethical approval was obtained from the DUT Institutional Research Ethics Committee (IREC) (Ethics clearance number REC 71/16) (Appendix L). In addition, the following ethical standards were specifically implemented:

- Participation was voluntary (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 participants' records were stored securely within a secure research storage facility within the Department of

Homoeopathy, and scheduled for shredding after 5 years in compliance with the DUT IREC requirements. When data was disseminated participants were referred to by unique participant numbers and their respective identities were not disclosed.

- Written informed consent was obtained from all participants prior to commencing the research project.
- All risks to participation were carefully considered and based on this consideration the study was determined to be of 'minimal risk'.
- Although placebo controlled, participants were informed of the possibility of receiving placebo and offered free treatment at the end of the study once un-blinding had taken place. Further, the implementation of placebo was not considered to be unethical in this context since the participants were not receiving any intervention for their ESS prior to recruitment.

3.6 CONSULTATIONS

3.6.1 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 were met (Including ESS >10).
- Physical examination and case history (See Appendix E).
- Explanation of research procedure.
- Explanation of how to complete the Stanford Sleepiness Scale.

3.6.2 FOLLOW UP CONSULTATION 1

This took place a minimum of 7 days after the first consultation.

The following took place at follow up consultation 1:

- 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 (14 days).

3.6.3 FOLLOW UP CONSULTATION 2

This took place a minimum of 14 days after follow up consultation 1.

The following took place at follow up consultation 2:

- Handing in of 14 days SSS by the patient (from the prior two weeks).
- 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.

3.7 DISPENSING AND DOSAGE

Each participant was provided with 25 ml of the individually chosen homoeopathic simillimum in 30CH potency (or placebo) in a 25 ml amber glass dropper bottle and the prescribed dosage was 10 drops placed directly under the tongue three times daily i.e. in the morning on waking, at midday and in the evening – participants were instructed to succuss (shake) the bottle 10 times before taking each dose.

3.8 INDIVIDUAL CASE ANALYSIS AND DETERMINATION OF THE HOMOEOPATHIC SIMILLIMUM

Individualising the case required the researcher to be free from prejudice, have healthy senses, be attentive while observing and have constancy in recording the picture of the disease (O'Reilly, 1996). O'Reilly, 1996 further states that during an investigation the researcher must distinguish whether the case is acute or chronic. Following detection of the disease, the researcher visualises, listens, and observes through the remaining senses what is altered or peculiar about the participant (O'Reilly, 1997). Symptoms should be recorded as the participant provides information about the condition; furthermore, the researcher should keep silent thus allowing the participant to utter everything without being interrupted (O Reilly,1996).

After listening to what was narrated by the participant, the researcher enquired so as to obtain precise information about each symptom, for example, the sensation of pain

of the participant, exact location, initial stages of pain, and the time of the day the pain began, and the longevity and the recurrence of pain (O'Reilly,1996). Questions by the researcher were open-ended thus avoiding simple yes or no answers (O'Reilly,1996). This prevented the false affirmation of things the participant may have been unsure of for convenience purposes (O'Reilly,1996).

The relevance of questions by the researcher were of higher quality only after the participant had given his/her account freely. In this regard, the participants' sensibilities were reliable (O'Reilly,1996). The researcher observed and noted the indications that were present prior to the condition being currently evaluated, as well as the present symptoms (O'Reilly,1996).

Case analysis was completed by the researcher as well as the supervisor as they thoroughly observed participants individually using the above-mentioned approach. The researcher and supervisor observed not only the physical aspects of the individualised case, but also the mental and emotional symptoms. Furthermore, past medical history was relevant so as to detect miasmatic influences (Vithoulkas, 1990). The degree of hypersensitivity to stimuli such as environmental and weather changes was assessed to evaluate the individuals' ability to maintain a stable equilibrium (Vithoulkas, 1990).

Repertorisation was completed using a computer programme (RADAR OPUS® version 24) which has an intuitive interface offering repertory and materia medica therefore linking all types of information required by the researcher.

Finding the simillimum is the core principle of homoeopathy as it profoundly initiates prescription of a single remedy (Vithoulkas, 1990). In this research the remedy was prescribed according to the totality of symptoms as elaborated in Chapter 2.

3.9 EVALUATION OF RESPONSE TO TREATMENT

3.9.1 MEASUREMENT TOOLS

3.9.1.1 Stanford Sleepiness Scale (SSS) (Hoddes et al., 1973)

The SSS was completed on a daily basis by each participant for a total of three weeks (21 days) i.e. for one week prior to commencing treatment (baseline data), followed by

an additional two weeks after commencing treatment. Participants rated their degree of sleepiness on an hourly basis throughout the awake period of the day using a s7-point Guttman scale (Bailes *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 (for statistical analysis 'X' was entered as a numerical value of 8)

3.9.1.2 **Epworth Sleepiness Scale (ESS)** (Johns, 1991)

The ESS was applied at the initial consultation as a component of the required inclusion criteria (See 3.2.1) i.e. served to confirm eligibility for participation. An ESS score of 10 or above was required to qualify for the study. The ESS was completed again at follow up consultation 1 (pre-treatment) and follow up consultation 2 (post-treatment) which was in due course compared with the baseline score.

Participants were asked how likely they were 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

Participants had to provide a likelihood score for the following settings:

- 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

The scores were totalled and ranged from 0-24, the higher the score the higher the degree of sleepiness (Bailes *et al*., 2006).

Participants chose the option which most suitably described how they were feeling at the time of testing (Bailes *et al*., 2006). Scoring 3 or more during periods when one should be alert was suggestive of one experiencing sleep debt.

3.9.2 DATA ANALYSIS

Quantitative data was inserted into an Excel spread sheet and was analysed by an appointed statistician. Additional descriptive statistics were presented in the form of bar charts, tables and graphs. The latest version of SPSS 24.0 was used to perform statistical analysis.

The repeated measures over time was the independent variable. The dependent variable is a treatment group to observe a group difference over time, similarly for age and gender.

The data was analysed using a combination of the parametric tests explained below.

3.9.2.1 ESS DATA ANALYSIS

The independent samples T-test: This was used to compare mean age standard deviation and standard error between the active and placebo groups.

Fischer's Test or Chi squared Test: Fischer's test provides an exact p value regardless of sample size. It was used to measure a significant difference at a 10% significance level between active group and placebo group over a three-week period. The Chi squared test was also used. However, it requires a larger sample size in order for it to provide an estimated p value.

Kolmogorov-Smirnov test or Shapiro-Wilk Test: Was used to determine whether the data was normally distributed. The Shapiro-Wilk test is good for smaller sample size preferably less than 50 but can handle a larger sample size.

Wilcoxon-Mann Whitney Test: This test was used to perform intergroup analysis for mean total scores at each interval over a three-week period.

3.9.2.2 SSS DATA ANALYSIS

Quantitative data was subjected to the GLM repeated measures ANOVA statistical techniques which were used to measure the effect of treatment at various time points both within the active and placebo groups.

CHAPTER 4: STATEMENT OF FINDINGS, INTERPRETATION AND DISCUSSION OF THE PRIMARY DATA

4.1 INTRODUCTION

In this chapter the statistical analysis of data obtained from the 2 groups used in this study will be discussed. The data was analysed using SPSS version 24.0.

Descriptive statistics are presented in the form of graphs and summary measures, including the mean, minimum, maximum and standard deviations.

The main aim of the analysis was to investigate whether the treatment did have an effect on the sleepiness scores based on the Epworth Sleepiness Scale and the Stanford Sleepiness Scale.

4.2 THE SAMPLE

Since there was no sample frame available on this population, non-probability sampling in the form of convenience sampling was applied whereby the first 31 consenting respondents who met the inclusion and exclusion criteria of the study were recruited. Participants were divided into 2 groups; the active (group 1) comprising 20 participants and the placebo (group 2) comprising 11 participants (n= 31).

4.3 SUMMARY STATISTICS

Table 4.1 provides the minimum, maximum, mean and standard deviation for the age of the participants. As can be seen there were 16 males and 15 females.

Table 4.1:Gender and age distribution of participants

group	Gender		N	Minimum	Maximum	Mean	Std. Deviation
Active	Male		10	19	26	21.20	1.989
	Female		10	19	28	22.60	2.459
Placebo	Male		6	20	24	21.17	1.472
	Female		5	18	27	21.20	3.421

In order to check whether there is a significant difference between the ages of participants in the Active group and Placebo group, an independent samples t-test was used. The mean age, standard deviation and standard error of the mean for the 2 groups are given in Table 4.2. The value of the t-statistic is t = 0.418 with degrees of freedom = 29 and corresponding p-value = 0.418, which is greater than 0.05, indicating that there is no significant difference in the mean ages of the participants in the two groups.

Table 4.2: Group distribution of participants

Group Statistics					
	group	N	Mean	Std. Deviation	Std. Error Mean
Age	Active	20	21.90	2.292	.512
	Placebo	11	21.18	2.401	.724

4.4 THE EPWORTH SLEEPINESS SCALE (ESS)

This is a simple, self-administered questionnaire that has been shown to provide a measurement of a subject's general level of daytime sleepiness (Johns, 1991). This scale does not question how frequently the participant is likely, for example, to fall asleep while watching television, as that will depend on how frequently the participant watches television (Johns, 1991). Instead the participant rates the chances of dozing off whenever they watch television. This provides a valid measurements of sleep propensity in adults (Johns, 1991).

This section analyses the scoring patterns of the participants per variable per section. The results are first presented using summarised means 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.

The ESS was applied at three intervals:

ESS_1 – at the initial consultation – where it served to confirm eligibility for participation i.e. an ESS score of 10 or above was required to qualify for inclusion.

ESS_2 – at the second consultation, immediately before commencement of treatment

ESS_3 – at the third consultation, after treatment and at the exit from the study

Participants were asked to rate 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 chance 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 with a possible range of 0-24; the higher the score the higher the degree of sleepiness (Bailes *et al.,* 2006).

4.4.1 Analysis of the daily ESS scores

The first ESS score (ESS_1) was obtained at the first consultation at recruitment stage and used as a qualifying criterion for inclusion i.e. if the total score was 10 or above, because such a score shows that the participant is well qualified for the study as it is indicative of having excessive daytime sleepiness. A comparison of ESS_1 scores between groups is presented in Table 4.3 and Figure 4.1. The Chi-squared value is 6.847, df = 3 and p-value = 0.077 which is significant at the 10% level (Fisher's exact

test gives a p-value of 0.057). This indicates that there was a difference in drowsiness patterns for the Active and Placebo group.

Table 4.3: Frequency distribution for ESS_1 total score for participants

			Never	Slight	Moderate	High	Total
group	Active	Count	1	4	12	3	20
		% within group	5.0%	20.0%	60.0%	15.0%	100.0%
	Placebo	Count	0	0	5	6	11
		% within group	0.0%	0.0%	45.5%	54.5%	100.0%
Total		Count	1	4	17	9	31
		% within group	3.2%	12.9%	54.8%	29.0%	100.0%

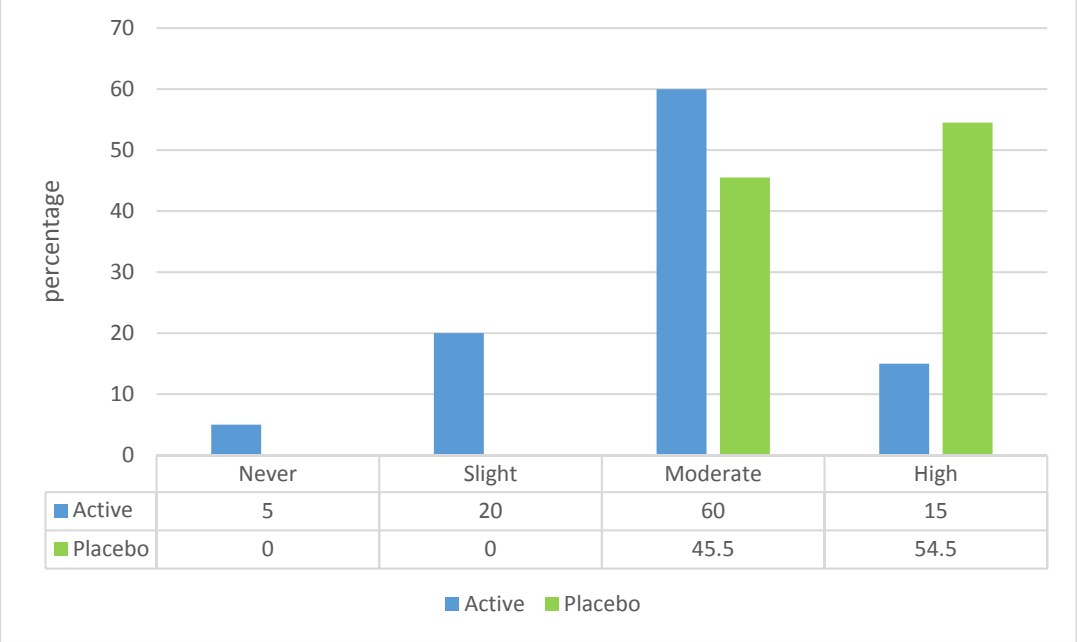

Figure 4.1: Comparison of ESS_1 Total scores for Active and Placebo groups

Table 4.4: Frequency distribution for ESS_2 for participants

			Never	Slight	Moderate	Total
group	Active	Count	9	6	5	20
		% within group	45.0%	30.0%	25.0%	100.0%
	Placebo	Count	2	8	1	11
		% within group	18.2%	72.7%	9.1%	100.0%
Total		Count	11	14	6	31
		% within group	35.5%	45.2%	19.4%	100.0%

The ESS_2 was administered on the second consultation prior to giving the participant the homeopathic similimum (Table 4.4 and Figure 4.2). This was done to observe the changes that may have occurred during the baseline which was a one-week interval. The Chi-squared value is 5.24, df = 2 and p-value = 0.073 which is significant at the 10% level. Fisher's exact test p-value = 0.077. This indicates that there was a difference in drowsiness patterns for the Active and Placebo group.

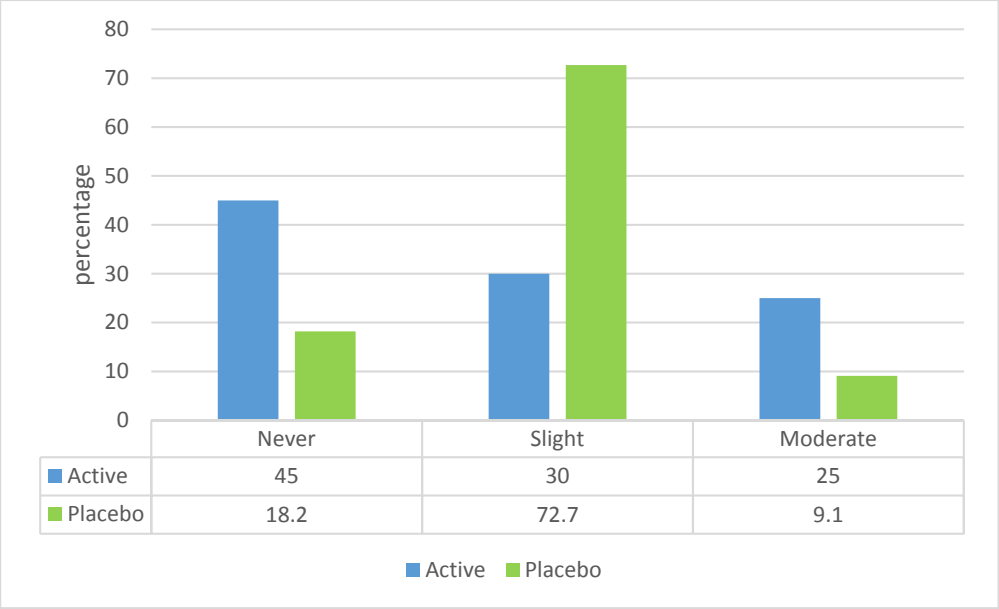

Figure 4.2: Comparison of ESS_2 Total scores for Active and Placebo groups

The ESS_3 was administered after the homeopathic simillimum was given to participants (Table 4.5 and Figure 4.3). In essence, it was administered on the final consultation to observe efficacy of the homeopathic simillimum in the management of excessive daytime sleepiness.

The only response pattern that showed a significant difference between Active and Placebo group at week 3 at a 10% level of significance was ESS_3_3 i.e. Sitting inactive in a public place (e.g. theatre or meeting), Chi-squared = 6.502, p = 0.079.

Table 4.5: Frequency distribution for ESS_3 for participants

			Never	Slight	Moderate	High	Total
group	Active	Count	5	8	7	0	20
		% within group	25.0%	40.0%	35.0%	0.0%	100.0%
	Placebo	Count	3	7	0	1	11
		% within group	27.3%	63.6%	0.0%	9.1%	100.0%
Total		Count	8	15	7	1	31
		% within group	25.8%	48.4%	22.6%	3.2%	100.0%

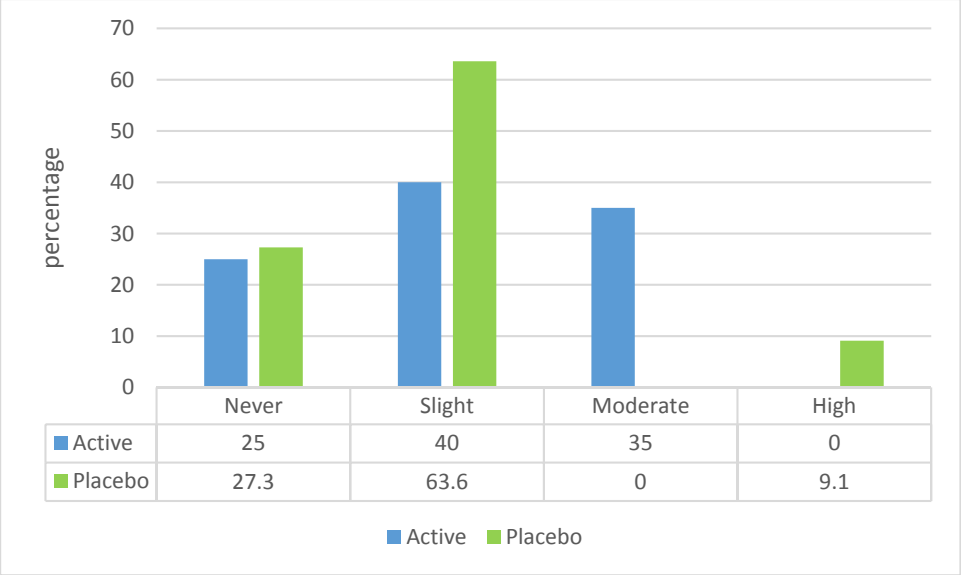

Figure 4.3: Comparison of ESS_3 Total scores for Active and Placebo groups

4.4.2 Analysis of selected ESS scores over time

4.4.2.1 ESS Situation No.1 (sitting and reading)

Table 4.6: Total percentage based on the chances of dozing off in setting No. 1 over 3 weeks

	ESS1_1 Active	ESS1_1Placebo	ESS2_1 Active	ESS2_1Placebo	ESS3_1 Active	ESS3_1Placebo
Never	5	0	5	0	25	9,1
Slight	20	0	25	9,1	55	36,4
Moderate	60	45,5	40	45,5	15	27,3
High	15	54,5	30	45,5	5	27,3

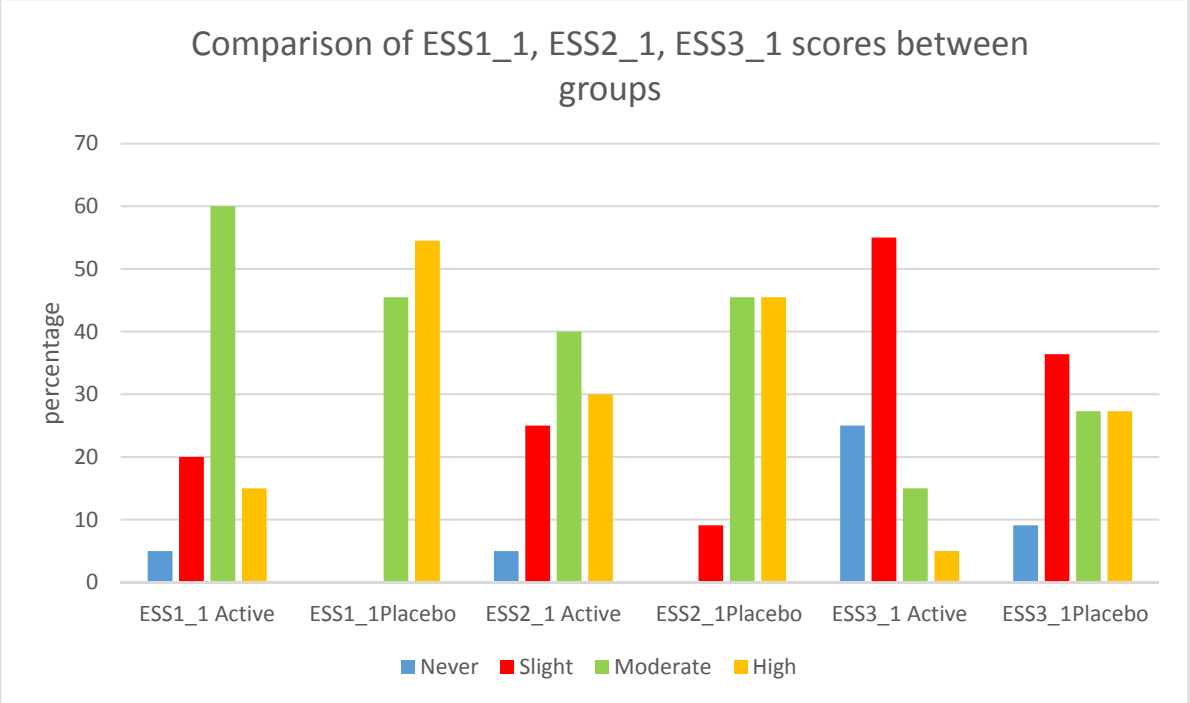

Figure 4.4: Bar chart showing the results obtained in Table 4.6. Comparison of setting No. 1 scores for ESS_1, ESS_2 and ESS_3 for each group

Table 4.6 and Figure 4.4 show that the percentage of participants in the active group who would 'never' doze off in this setting increased from 5% to 25% (20%) of this group and the proportion of participants in the active group with a 'slight' change of dozing off in this setting increased by 30% (from 25%-55%). This is attributable to the reduction and migration of the percentage in the 'moderate' and 'high' categories which both decreased by 25% respectively.

Although the percentage of participants in the placebo group who would 'never' doze off in this setting also increased, the increase was relatively less at 9.1%. There was a 27% increase in the proportion of those with a 'slight' chance of dozing off attributable to the reductions in the 'moderate' and 'high' categories were also relatively less at 18% in respectively.

In this setting a reduction in the chance of dozing off took place in both groups however the reduction in the active group was more apparent.

4.4.2.2 ESS situation setting No. 3 (sitting in a public place e.g. a theatre or a meeting)

Table 4.7: Total percentage based on chances of dozing off in setting No. 3 over 3 weeks

	ESS1_3 Active	ESS1_3 Placebo	ESS2_3 Active	ESS2_3 Placebo	ESS3_3 Active	ESS3_3 Placebo
Never	20	0	15	18,2	25	27,3
Slight	30	45,5	30	27,3	40	63,6
Moderate	40	18,2	40	27,3	35	0
High	10	36,4	15	27,3	0	9,1

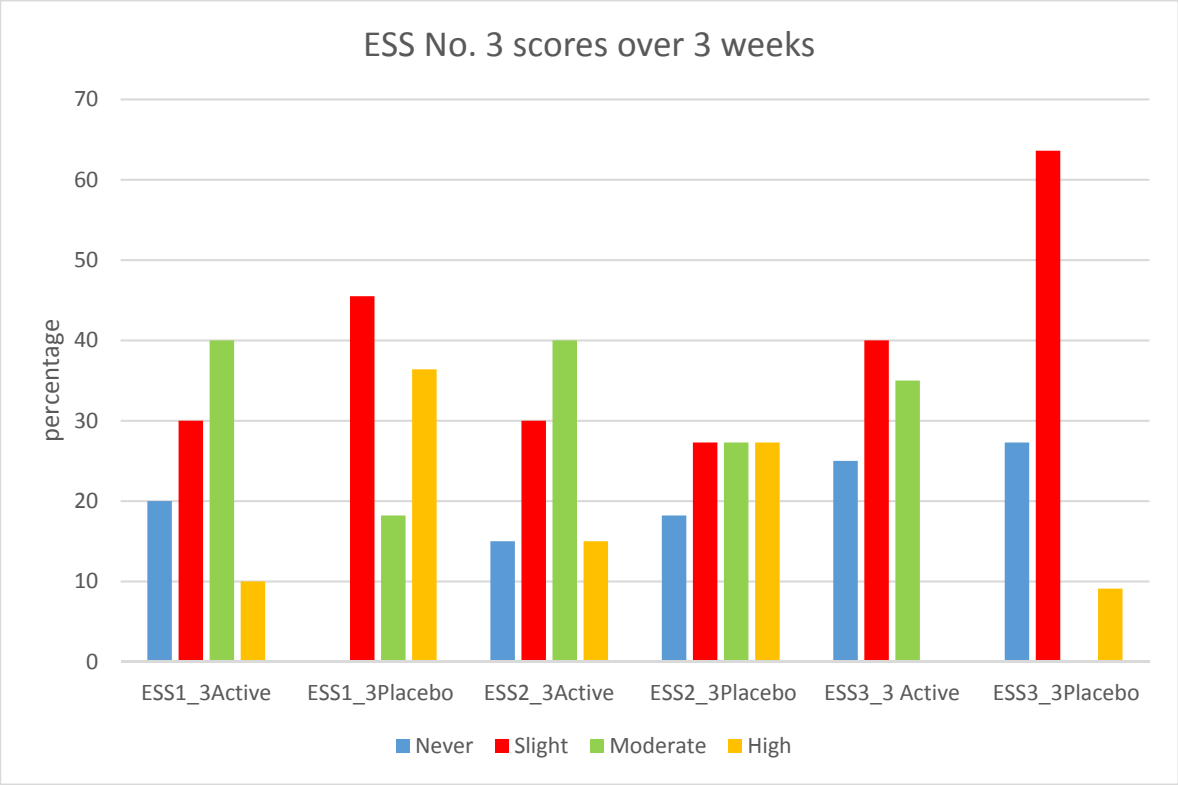

Figure 4.5: Graph shows the results obtained from Table 4.7

Both those in the Active and Placebo groups experienced improvements in sleepiness in this setting with a reduction in 'high' and 'moderate' chances of dozing off by 15% and 5% respectively and proportionate increases in those with 'slight' or 'never' dozing off in this setting increasing by 10% respectively. There was a decrease of 18% and 27% in 'high' and 'moderate' scoring placebo participants respectively.

4.4.2.3 ESS situation no 6 (sitting and talking to someone)

Table 4.8: Total percentage based on the chances of dozing in setting No. 6 over 3 weeks

	ESS1_6 Active	ESS1_6 Placebo	ESS2_6 Active	ESS2_6 Placebo	ESS3_6 Active	ESS3_6 Placebo
Never	55	45,5	45	18,2	70	45,5
Slight	30	45,5	30	72,7	30	27,3
Moderate	15	9,1	25	9,1	0	18,2
High	0	0	0	0	0	9,1

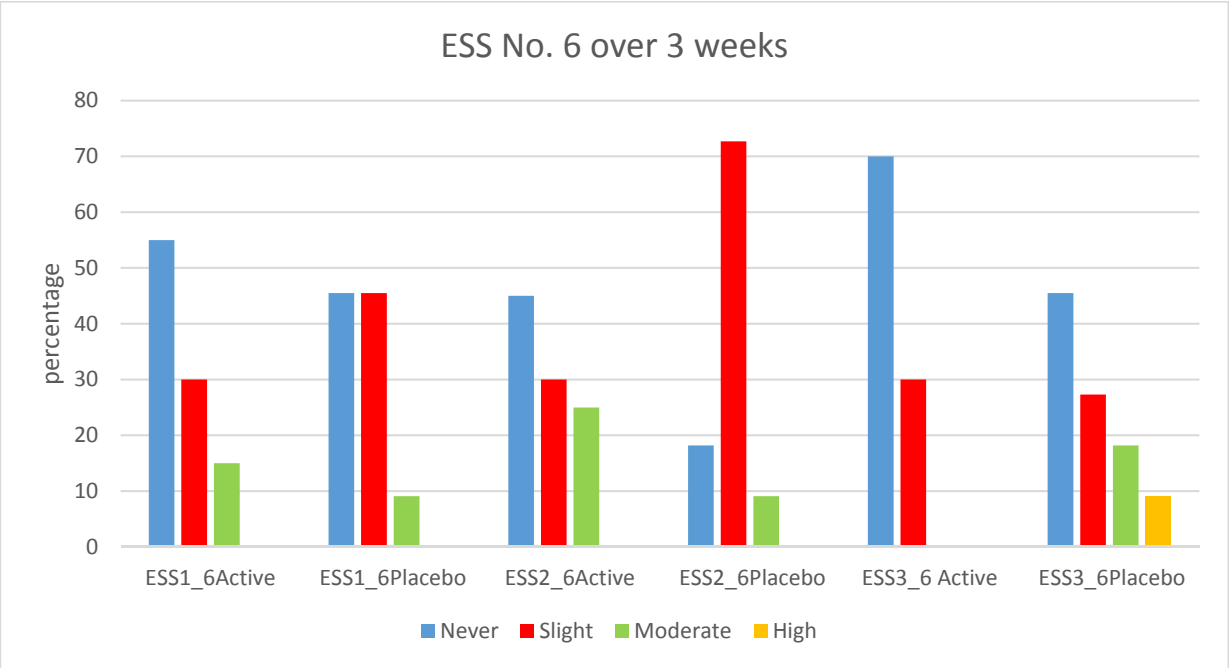

Figure 4.6: Comparison of the ESS for setting No.6

The data shows that the percentage of 'moderate' scoring participants in the active group decreased by 25% (there were no 'high' scoring participants in either group for this setting at baseline) i.e. by the end of the study the percentage of participants with a moderate chance of dozing off in this setting was 0%. Similarly, the percentage of participants in the Active group that would 'never' doze off in this setting increased by 25% i.e. at the close of the study 70% of the Active group would 'never' doze off in this setting.

Placebo participants appeared to become sleepier in this setting with a 9% increase in those with 'high' chance of dozing (0% at high risk at baseline), and also a 9% increase in those with 'moderate' risk of dozing in this setting.

4.4.3 Analysis of the Total ESS score

The ESS is easy to administer as it is based on questions referring to eight situations (see Appendix D). Participants were asked to rate on a scale of 0-3 the likelihood of dozing off in the eight situations based on their usual way of life in recent times (Johns, 1991). The total score was calculated by adding the individual scores for each of the eight settings i.e. minimum of 0 and maximum of 24. Means were calculated for each group at each measurement interval and then analysed using either the Kolmogorov-Smirnov test or the Shapiro-Wilk test to determine if the data was normally distributed. This was followed by the Wilcoxon-Mann Whitney test used to perform inter-group analysis for mean total scores at each interval over a three-week period.

4.4.3.1 Descriptive statistics – ESS Mean Total scores

Descriptive statistics for total ESS scores by group and by measurement interval are presented in Tables 4.9 (Active group) and 4.10 (Placebo group). Mean total scores for the Active group decreased by 5.75 points and by 4.64 points in the Placebo groups between consultations 2 and 3.

Table 4.9: Descriptives for the ESS-TOT variables for the active groups

Descriptives[a]				
			Statistic	Std. Error
ESS_1_TOT	Mean		13.10	.611
	95% Confidence Interval for Mean	Lower Bound	11.82	
		Upper Bound	14.38	
	Median		12.50	
	Variance		7.463	
	Std. Deviation		2.732	
	Minimum		10	
	Maximum		20	
	Range		10	
ESS_2_TOT	Mean		14.25	.714
	95% Confidence Interval for Mean	Lower Bound	12.76	
		Upper Bound	15.74	
	Median		15.00	
	Variance		10.197	
	Std. Deviation		3.193	
	Minimum		10	
	Maximum		21	
	Range		11	

ESS_3_TOT	Mean		8.50	.829
	95% Confidence Interval for Mean	Lower Bound	6.77	
		Upper Bound	10.23	
	Median		8.00	
	Variance		13.737	
	Std. Deviation		3.706	
	Minimum		2	
	Maximum		16	
	Range		14	

Table 4.10: Descriptives for ESS-TOT variables for the placebo group

Descriptives[a]				
			Statistic	Std. Error
ESS_1_TOT	Mean		14.36	.975
	95% Confidence Interval for Mean	Lower Bound	12.19	
		Upper Bound	16.54	
	Median		13.00	
	Variance		10.455	
	Std. Deviation		3.233	
	Minimum		10	
	Maximum		19	
	Range		9	
ESS_2_TOT	Mean		14.91	.958
	95% Confidence Interval for Mean	Lower Bound	12.78	
		Upper Bound	17.04	
	Median		14.00	
	Variance		10.091	
	Std. Deviation		3.177	
	Minimum		10	
	Maximum		20	
	Range		10	
ESS_3_TOT	Mean		10.27	1.585
	95% Confidence Interval for Mean	Lower Bound	6.74	
		Upper Bound	13.80	
	Median		11.00	
	Variance		27.618	
	Std. Deviation		5.255	
	Minimum		0	
	Maximum		20	
	Range		20	

4.4.3.2 Testing normality of data – ESS Mean Total scores

In order to conduct the statistical tests for differences from week to week it was necessary to check the normality of the ESS_TOT variables. This was accomplished by using either the Kolmogorov-Smirnov test or the Shapiro-Wilk test. The results of these tests for the variables of interest are given in Table 4.11.

Table 4.11: Descriptives based on the ESS-TOT variables using Kolmogorov-Smirnov test and Shapiro-Wilk's test

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
ESS_1_TOT	.252	31	.000	.891	31	.004
ESS_2_TOT	.133	31	.175	.938	31	.071
ESS_3_TOT	.119	31	.200*	.983	31	.882
*. This is a lower bound of the true significance.						
a. Lilliefors Significance Correction						

To confirm the violation of normality, the stem-and-leaf plot in Figure 4.7 shows that the data was not normal. Similarly, there was not strong evidence that ESS_2_TOT and ESS_3_TOT are normally distributed.

```
ESS_1_TOT Stem-and-Leaf Plot

 Frequency     Stem &  Leaf

     7,00        1 .  0000011
    14,00        1 .  22222233333333
     2,00        1 .  55
     4,00        1 .  6667
     3,00        1 .  999
     1,00        2 .  0

 Stem width:    10
 Each leaf:        1 case(s)
```

Figure 4.7: Stem-and-leaf plot

4.4.3.3 Inter-group comparison of ESS Total scores

It is good statistical practice to use nonparametric methods if the normality assumption is violated. The Wilcoxon-Mann-Whitney test was thus used to test whether the median values of the Active and Placebo group differed. The results of the Wilcoxon-Mann-Whitney test are summarised in Table 4.12.

Table 4.12: Inter-group analysis of Total ESS scores

Variable	p-value
ESS_1_TOT	0.261
ESS_2_TOT	0.670
ESS_3_TOT	0.261

There was no statistical difference between Total ESS scores between groups at the three respective intervals. However, it is interesting to note the change in the average scores over time. The table below summarises these averages and Figure 4.8 depicts the trend over the 3-week period.

Table 4.13: Comparison of means between the active group and placebo groups over the 3-week period

Week	Active	Placebo
Week 1	13.10	14.36
Week 2	14.25	14.91
Week 3	8.50	10.27

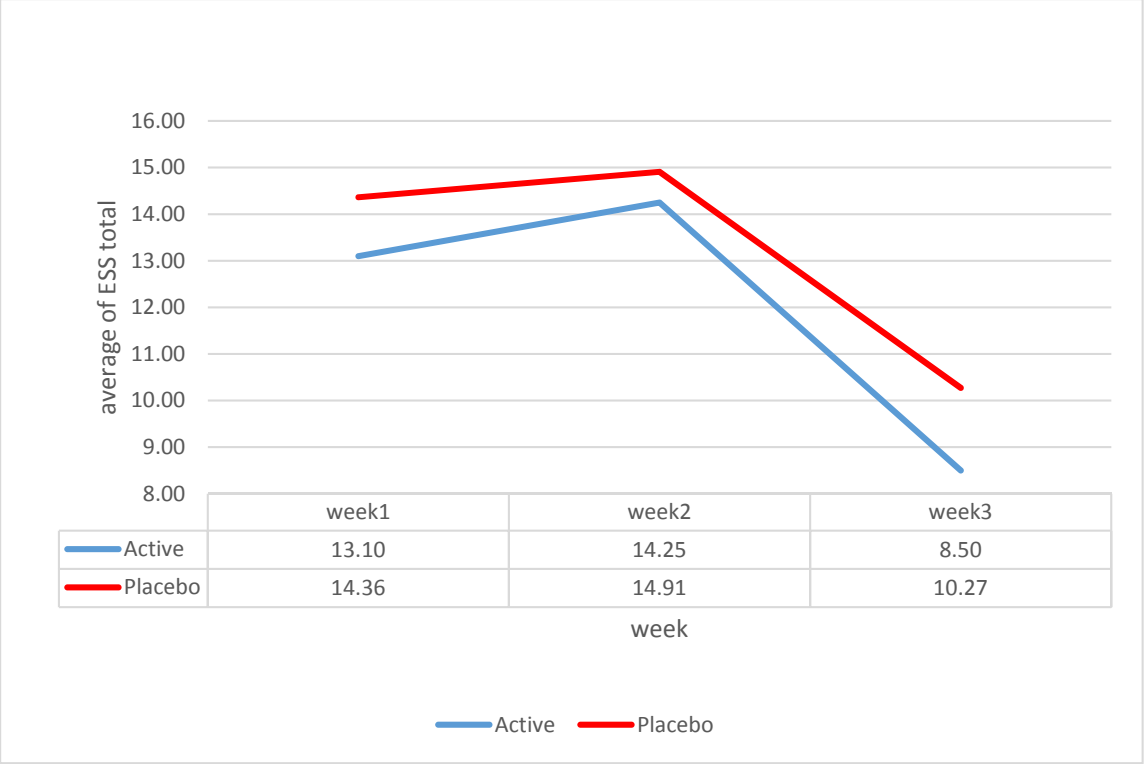

Figure 4.8: Graphical presentation of means between Active and Placebo groups over a 3-week period

Mean Total ESS scores decrease over time for both the Active and the Placebo groups i.e. 5.75 and 4.64 respectively between weeks 2 and 3. This is equivalent to a 40% reduction in the Active group and a 31% reduction in the Placebo group.

A multivariate repeated measures analysis was conducted to test for a group difference and a difference in scores across time. The multivariate test gave a Wilk's lambda ($F = 14.932$, $p < 0.001$) for the variable "week" indicating a highly significant change over time (as can be seen from Figure 4.8). There was however no "week*group" interaction effect, ($F = 0.252$, $p = 0.779$). This can also be seen from Figure 4.8, since the profiles for the groups are practically parallel and show a similar trend across time.

The test for "within-subjects" confirmed the multivariate results that "week" is highly significant ($F = 25.67$, $p < 0.001$) and there is no "week*group" interaction effect ($F = 0.69$, $p = 0.71$). Table 4.14 shows that there is a highly significant linear and quadratic effect over time, which is also evident from Figure 4.8 ($F = 26.9$, $p < 0.001$ and $F = 23.97$, $p < 0.001$).

Table 4.14: Tests of within subjects contrasts

Measure: time						
Source	week	Type III Sum of Squares	df	Mean Square	F	Sig.
week	Linear	268.016	1	268.016	26.908	.000
	Quadratic	172.653	1	172.653	23.967	.000
week * group	Linear	.920	1	.920	.092	.763
	Quadratic	3.492	1	3.492	.485	.492
Error(week)	Linear	288.855	29	9.961		
	Quadratic	208.906	29	7.204		

Table 4.15 shows that there is no group effect, F = 1.614, p = 0.214, which confirms that the average ESS_TOT scores do not differ for the Placebo and Active groups. This can also be seen from Figure 4.8 since the graphs across time are very similar.

Table 4.15: Tests of within subject effects

Transformed Variable: Average					
Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	13447.144	1	13447.144	671.864	.000
group	32.305	1	32.305	1.614	.214
Error	580.426	29	20.015		

4.4.4 Intra-group comparison of ESS Total scores

4.4.4.1 Active group analysis

Table 4.16: Descriptive statistics for the Active group

Descriptive Statistics[a]					
	N	Minimum	Maximum	Mean	Std. Deviation
ESS_1_TOT	20	10	20	13.10	2.732
ESS_2_TOT	20	10	21	14.25	3.193
ESS_3_TOT	20	2	16	8.50	3.706
Valid N (listwise)	20				

Table 4.16 provides the descriptive statistics for the active group. In week 3 the mean of 8.50 indicates that there has been an improvement in the score.

Table 4.17: Correlations of paired samples for Active groups

Paired Samples Correlations[a]				
		N	Correlation	Sig.
Pair 1	ESS_1_TOT & ESS_2_TOT	20	.534	.015
Pair 2	ESS_2_TOT & ESS_3_TOT	20	-.300	.198
Pair 3	ESS_1_TOT & ESS_3_TOT	20	-.135	.570

Table 4.17 shows that there is significant correlation between weeks 1 and 2 (r = 0.534 and p = 0.015) in the active group and a weak negative correlation between scores for pairs of observations in weeks 2 and 3 and 1 and 3, with both p-values > 0.05.

Table 4.18: Paired samples test for Active group

Paired Samples Test[a]							
		Paired Differences			t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean			
Pair 1	ESS_1_TOT - ESS_2_TOT	-1.150	2.889	.646	-1.780	19	.091
Pair 2	ESS_2_TOT - ESS_3_TOT	5.750	5.571	1.246	4.616	19	.000
Pair 3	ESS_1_TOT - ESS_3_TOT	4.600	4.893	1.094	4.205	19	.000

There was a significant difference (decrease) in the mean ESS Total scores for the Active group between week 1 and week 3 and similarly a significant difference between the mean ESS Total scores for week 2 and week 3, with both p-values < 0.001. This confirms that there was significant improvement within this group over time in response to the active treatment. There is not a significant difference between mean ESS Total scores for weeks 1 and 2 and this was expected, since the intervention was only administered at week 2.

4.4.4.2 Placebo group analysis

Table 4.19: Descriptive statistics per week for ESS Total scores

Descriptive Statistics[a]					
	N	Minimum	Maximum	Mean	Std. Deviation
ESS_1_TOT	11	10	19	14.36	3.233
ESS_2_TOT	11	10	20	14.91	3.177
ESS_3_TOT	11	0	20	10.27	5.255
Valid N (listwise)	11				

The descriptive statistics for the ESS Total scores for the placebo group are given in Table 4.19. This reveals an improvement in week 3 with a mean of 10.27.

Table 4.20: Paired samples correlations for ESS Totals

Paired Samples Correlations[a]				
		N	Correlation	Sig.
Pair 1	ESS_1_TOT & ESS_2_TOT	11	.890	.000
Pair 2	ESS_2_TOT & ESS_3_TOT	11	.696	.017
Pair 3	ESS_1_TOT & ESS_3_TOT	11	.759	.007

Table 4.20 shows the significant positive correlations in all ESS Total scores pairs with p-values < 0.05.

Table 4.21: Paired samples test for Placebo group

Paired Samples Test[a]							
		Paired Differences			t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean			
Pair 1	ESS_1_TOT - ESS_2_TOT	-.545	1.508	.455	-1.200	10	.258
Pair 2	ESS_2_TOT - ESS_3_TOT	4.636	3.802	1.146	4.045	10	.002
Pair 3	ESS_1_TOT - ESS_3_TOT	4.091	3.506	1.057	3.870	10	.003

Similarly, there was a significant difference in the mean ESS Total scores for the Placebo group between week 1 and week 3 and similarly a significant difference between the mean ESS Total scores for week 2 and week 3, with both p-values < 0.001. Thus, participants in the Placebo group improved significantly over time.

4.5 STANFORD SLEEPINESS SCALE (SSS):

The Stanford Sleepiness Scale is one of the most widely used subjective sleepiness-measuring instruments that is used to quantify short-term changes in sleepiness (Sahid et al. 2010). It consists of a seven-point scale of intervals varying from very alert (1) to excessively sleepy (7) (Herscovitch and Broughton, 1981).

4.5.1 Comparison of SSS scores by hour for placebo and active group

In terms of the SSS, Participants rated their degree of sleepiness on an hourly basis throughout the awake period of the day using a 7-point Guttman scale (Bailes *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 chose the option which most suitably described how they felt at the time of testing (Bailes *et al.,* 2006). Scoring three or more during periods when one should be alert is suggestive of one experiencing sleep debt and more sleep is required.

SSS data was captured hourly from 7:00am to 12:00am (see Appendix C); the data used for statistical analysis were those gathered during the 'awake' period of the day i.e. 7:00am to 7:00pm as the tool was applied in the context of EDS.

4.5.1.1 Statistical analysis of SSS for week 1

Table 4.22: Descriptive statistics per hour for week 1 in the Active group

Descriptive Statistics[a]					
	N	Minimum	Maximum	Mean	Std. Deviation
w1_7tot	20	7.00	56.00	30.4000	15.52384
w1_8tot	20	7.00	56.00	28.9500	14.79856
w1_9tot	20	7.00	56.00	26.7000	14.62910
w1_10tot	20	7.00	42.00	22.1000	10.67659
w1_11tot	20	7.00	36.00	19.1500	8.56108
w1_12tot	20	7.00	33.00	20.9500	7.59137
w1_13tot	20	9.00	35.00	22.5500	8.54385
w1_14tot	20	7.00	38.00	22.4500	9.42826
w1_15tot	20	7.00	42.00	22.9500	10.20565
w1_16tot	20	7.00	39.00	23.2500	9.32385
w1_17tot	20	7.00	39.00	24.0000	9.70079

w1_18tot	20	7.00	49.00	28.2000	9.74733
w1_19tot	20	9.00	56.00	27.8000	10.86084
Valid N (listwise)	20				

As can be seen from Table 4.22, the sleepiness score was highest at 7:00am (mean = 30.4) and lowest at 11:00am (mean = 19.15). The standard deviation was also highest at 7:00am (std. deviation = 15.52) and lowest at 12:00pm (std. deviation = 7.59).

Table 4.23: Descriptive statistics per hour for week 1 in the Placebo group

Descriptive Statistics[a]					
	N	Minimum	Maximum	Mean	Std. Deviation
w1_7tot	11	13.00	56.00	36.0909	16.17686
w1_8tot	11	14.00	56.00	30.4545	16.71744
w1_9tot	11	8.00	54.00	24.6364	15.48078
w1_10tot	11	8.00	56.00	21.1818	16.11098
w1_11tot	11	9.00	50.00	19.2727	11.45505
w1_12tot	11	8.00	28.00	16.8182	6.98310
w1_13tot	11	9.00	27.00	17.9091	5.64720
w1_14tot	11	7.00	33.00	20.2727	8.31975
w1_15tot	11	8.00	31.00	21.9091	8.27592
w1_16tot	11	11.00	44.00	25.6364	8.60550
w1_17tot	11	15.00	46.00	27.4545	8.55995
w1_18tot	11	16.00	46.00	28.1818	8.69273
w1_19tot	11	7.00	48.00	29.1818	12.99091
Valid N (listwise)	11				

As can be seen from Table 4.23 and Figure 4.9, the sleepiness score was highest at 7:00am (mean = 36.09) and lowest at 12:00pm (mean = 16.81). The standard deviation is highest at 8:00am (std. deviation = 16.71) and lowest at 1:00pm (std. deviation = 5.65).

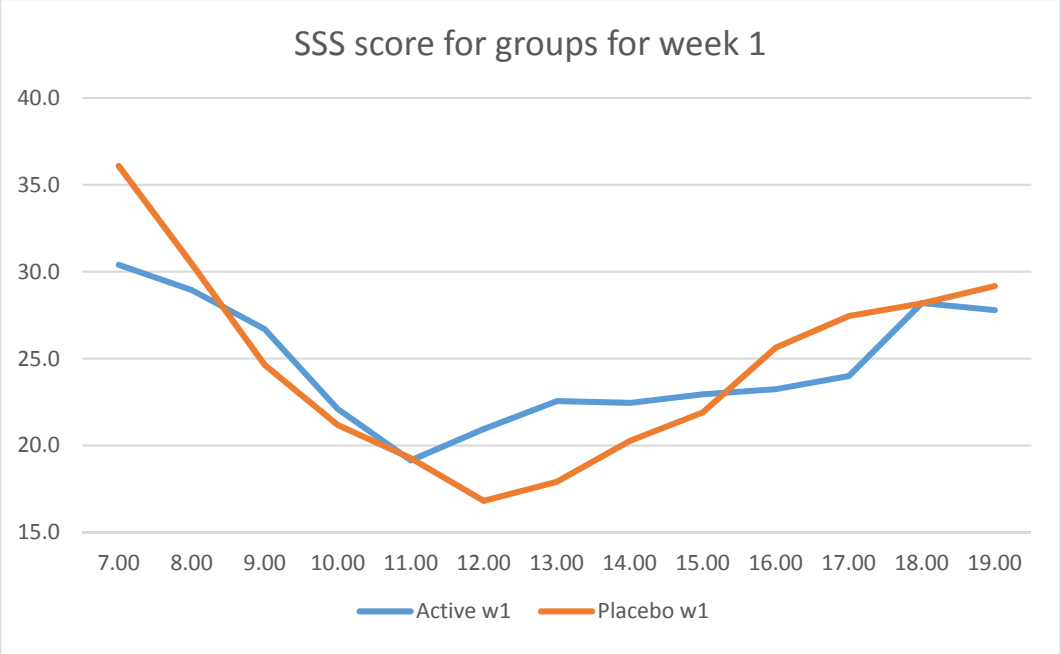

Figure 4.9: Repeated measures model for SSS for groups over week 1

The following paragraph gives the results from a repeated measures ANOVA. This is done by fitting a general linear model, which accounts for repeated measures over time in this instance. Generally, Figure 4.9 indicates that both groups were most sleepy in the morning at 7:00am and less so between 11:00am and 12:00pm, both groups become more sleepy towards evening.

Table 4.24: Tests of within-subjects effects

Tests of Within-Subjects Effects							
Measure: Sleepiness							
Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Time	Greenhouse-Geisser	6699.001	2.385	2809.346	6.617	.001	.186
Time*group	Greenhouse-Geisser	736.103	2.385	308.698	.727	.510	.024

There is a significant change over time (F = 6.62, p-value = 0.001) as seen in table 4.24. There is a significant quadratic trend over time (F = 16.9, p < 0.001). This can be seen in the Figure 4.9.

There is no time*group interaction effect. This provides an indication of higher chances of dozing at 7am of both groups, then less chances of dozing between 11:00am and 1:00pm and a slight increase of sleepiness from 2:00pm till late.

Table 4.25: Tests between-subjects effects

Tests of Between-Subjects Effects						
Measure: Sleepiness						
Transformed Variable: Average						
Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Intercept	222521.212	1	222521.212	349.647	.000	.923
group	.111	1	.111	.000	.990	.000
Error	18456.073	29	636.416			

Table 4.25 shows that there is not a significant group effect. This means there is no significant difference between the means for Active and Placebo groups during week 1 – this is to be expected since week 1 was the pre-treatment/baseline period. A 95% confidence interval for the difference between Active and Placebo is (-5.34, 5.41).

4.5.1.2 Statistical analysis of SSS for week 2

Table 4.26: Descriptive statistics per hour for week 2 in the Active group

Descriptive Statistics[a]					
	N	Minimum	Maximum	Mean	Std. Deviation
w2_7tot	20	7.00	56.00	29.9500	16.98134
w2_8tot	20	7.00	56.00	22.5500	15.15699
w2_9tot	20	7.00	56.00	22.5000	13.62467
w2_10tot	20	7.00	40.00	18.7500	9.90946
w2_11tot	20	7.00	39.00	16.1000	9.22753
w2_12tot	20	7.00	30.00	15.0000	7.45513
w2_13tot	19	7.00	29.00	16.3158	7.36397
w2_14tot	20	7.00	36.00	17.8000	7.77716
w2_15tot	20	7.00	37.00	18.8500	8.88686
w2_16tot	20	7.00	36.00	21.4000	9.03444
w2_17tot	20	7.00	42.00	21.3500	9.01037
w2_18tot	20	7.00	41.00	20.7000	9.97418
w2_19tot	20	7.00	40.00	22.0000	10.88698
Valid N (listwise)	19				

Table 4.26 shows that the sleepiness score in the Active group at week 2 was highest at 7:00am (mean = 29.95) and lowest at 12:00pm (mean = 15.00). The standard deviation was highest at 7:00am (std. deviation = 16.98) and lowest at 1:00pm (std. deviation = 7.36). This group's most sleepy time of day remained unchanged at 7:00am; however, the most alert time of day moved 1 hour later to 12:00pm.

Table 4.27: Descriptive statistics per hour for week 2 in the Placebo group

Descriptive Statistics[a]					
	N	Minimum	Maximum	Mean	Std. Deviation
w2_7tot	10	13.00	56.00	34.7000	13.94473
w2_8tot	10	13.00	50.00	26.8000	12.81319
w2_9tot	10	7.00	48.00	20.2000	11.68855
w2_10tot	10	7.00	45.00	16.9000	11.40614
w2_11tot	10	9.00	45.00	17.8000	10.96256
w2_12tot	10	11.00	45.00	19.0000	10.61446
w2_13tot	10	10.00	33.00	19.4000	7.30601
w2_14tot	10	10.00	35.00	20.4000	8.75849
w2_15tot	10	9.00	37.00	20.7000	8.02842
w2_16tot	10	16.00	33.00	22.0000	6.03692
w2_17tot	10	18.00	34.00	24.3000	5.57873
w2_18tot	10	14.00	37.00	26.2000	7.17712
w2_19tot	10	17.00	37.00	27.3000	6.48160
Valid N (listwise)	10				

Table 4.27 shows that the sleepiness score was at its highest at 7:00am (mean = 34.70) and lowest at 10:00am (mean = 16.90). The standard deviation was highest at 7.00 in the morning (std. deviation = 13.94) and lowest at 1:00pm (std. deviation = 7.31). In this group the sleepiest time of day remained unchanged at 7:00am; however, the most alert time of day moved 2 hours earlier to 10:00am.

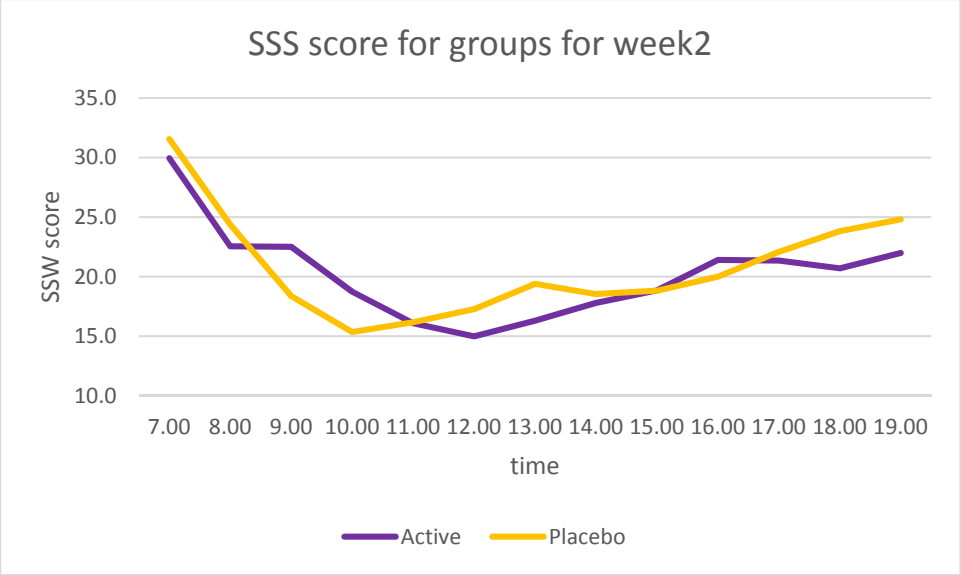

Figure 4.10: Repeated measures model for SSS for groups over week 2

In this paragraph the repeated measures model for SSS for the groups for week 2 is presented.

Table 4.28: Tests of within-subjects effects

Tests of Within-Subjects Effects							
Measure: sleepiness							
Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
time	Greenhouse-Geisser	6059.708	2.908	2083.815	7.459	.000	.216
time*group	Greenhouse-Geisser	485.713	2.908	167.027	.598	.613	.022

As shown in Table 4.28, the time effect of F = 7.46, p-value < 0.001 is significant. However, the interaction between time and the groups together reveals that F = 0.598 and p-value = 0.61). Since the p-value is greater than 0.05 this indicates that there is no significant interaction between groups and time as the p-value is 0.61.

Table 4.29: Tests of within-subjects contrasts

Tests of Within-Subjects Contrasts							
Measure							
Source	time	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
time	Linear	117.283	1	117.283	.345	.562	.013
	Quadratic	4768.209	1	4768.209	30.248	.000	.528
	Cubic	1109.461	1	1109.461	11.832	.002	.305

As shown in Table 4.29, there appears to be a quadratic and a cubic trend of SSS over time (F = 30.25, p-value < 0.001 and F = 11.83, p-value = 0.002). This means that the SSS Total scores differ when comparing the active and placebo groups over time.

Table 4.30: Tests of between-subjects effects

Tests of Between-Subjects Effects						
Measure: sleepiness						
Transformed Variable: Average						
Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Intercept	162183.095	1	162183.095	284.516	.000	.913
group	293.228	1	293.228	.514	.479	.019
Error	15390.826	27	570.031			

From Table 4.30 we see that the group effect is not significant (F = 0.514, p-value = 0.48). This means that the mean SSS Total score does not differ for the Active and Placebo groups at week 2. A 95 % confidence interval for the difference between the Active and Placebo is (-7.16, 3.45).

4.5.1.3 Statistical analysis of SSS for week 3

Table 4.31: Descriptive statistics per hour for week 3 in the Active group

Descriptive Statistics[a]					
	N	Minimum	Maximum	Mean	Std. Deviation
w3_7tot	20	7.00	56.00	24.1500	16.55064
w3_8tot	20	7.00	48.00	21.1500	13.12801
w3_9tot	20	7.00	48.00	17.9000	11.52526
w3_10tot	20	7.00	37.00	14.5000	8.03610

w3_11tot	20	7.00	37.00	13.1000	7.64268
w3_12tot	20	7.00	30.00	13.4500	6.03913
w3_13tot	20	7.00	25.00	14.1500	4.74924
w3_14tot	20	7.00	19.00	13.1500	3.77352
w3_15tot	20	7.00	49.00	14.7500	9.15869
w3_16tot	20	7.00	27.00	14.6500	5.90517
w3_17tot	20	7.00	27.00	16.0500	6.22791
w3_18tot	19	7.00	29.00	16.0000	7.16473
w3_19tot	19	7.00	38.00	19.2632	8.63354
Valid N (listwise)	18				

The sleepiness score was highest at 7.00 in the morning (mean = 24.15) and lowest at 11.00 (mean = 13.10). The standard deviation was highest at 7.00 in the morning (std. deviation = 16.55) and lowest at 13.00 (std. deviation = 3.77). The sleepiest time of day remained 7:00 and the most alert time moved earlier by one hour to 11:00.

Table 4.32: Descriptive statistics per hour for week 3 in the Placebo group

Descriptive Statistics[a]					
	N	Minimum	Maximum	Mean	Std. Deviation
w3_7tot	10	7.00	56.00	34.8000	19.45251
w3_8tot	10	7.00	56.00	32.8000	17.80012
w3_9tot	10	7.00	51.00	19.8000	14.52048
w3_10tot	10	7.00	51.00	16.9000	14.91047
w3_11tot	10	8.00	46.00	16.3000	11.70043
w3_12tot	10	10.00	47.00	17.1000	11.06998
w3_13tot	10	9.00	47.00	16.6000	11.13752
w3_14tot	10	9.00	40.00	16.7000	8.99444
w3_15tot	10	7.00	36.00	17.7000	8.21989
w3_16tot	10	9.00	38.00	17.5000	8.23610
w3_17tot	10	13.00	47.00	22.5000	11.85327
w3_18tot	10	12.00	40.00	21.1000	8.71079
w3_19tot	10	7.00	41.00	23.1000	10.49285
Valid N (listwise)	10				

The sleepiness score was highest at 7:00am (mean = 34.80) and lowest at 11:00am (mean = 16.30). The standard deviation was highest at 7:00am (std. deviation = 19.45) and lowest at 1:00pm (std. deviation = 8.22). The sleepiest time of day remained

7:00am in this group and the most alert time was one hour later at 11:00am in week 3.

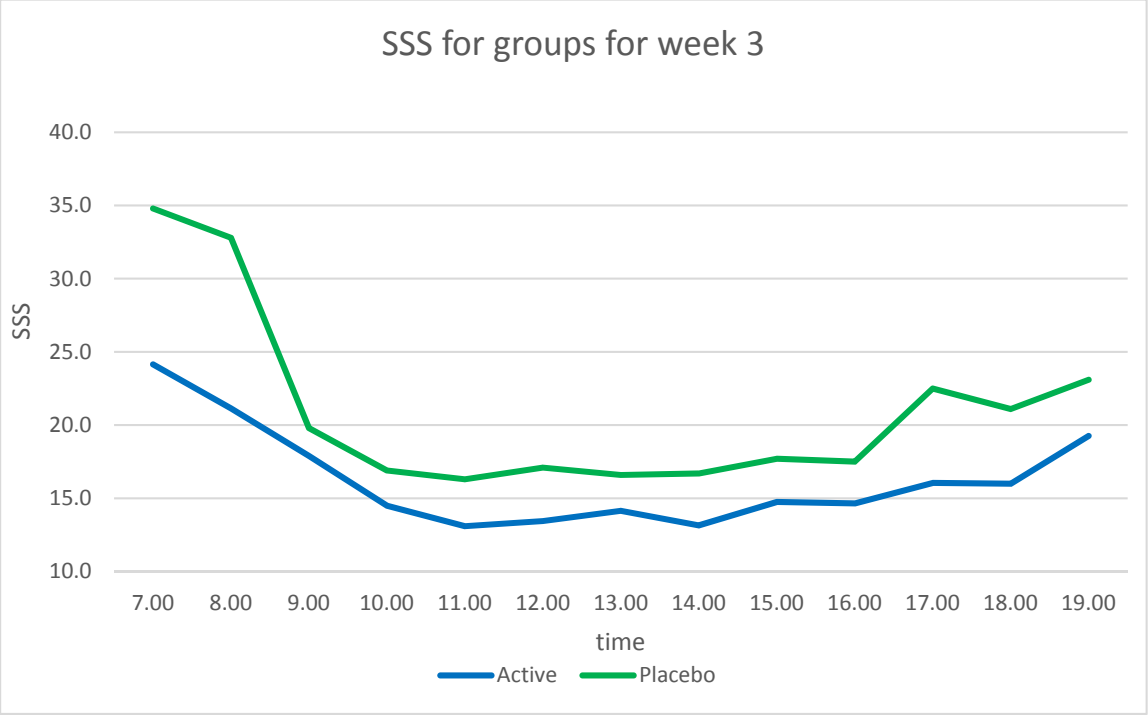

Figure 4.11: Repeated measures model for SSS for groups over week 3

Figure 4.11 clearly indicates congruency between groups with respect to the degree of sleepiness during the wake period.

Table 4.33: Tests of within-subjects effects

Tests of Within-Subjects Effects							
Measure: Sleepiness							
Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
time	Greenhouse-Geisser	6798.278	2.595	2620.037	8.521	.000	.247
group*time	Greenhouse-Geisser	769.376	2.595	296.516	.964	.405	.036

From Table 4.33 we see that there is a significant time effect (F = 8.5, p-value < 0.001). There is not a significant group*time interaction effect (F = 0.96, p-value = 0.405) Therefore, this indicates that when time (independent variables) interacts with the groups (active and placebo) as dependent variables this gives a result showing the

indifference of the whole interaction. However, time on its own provides a positive effect.

Table 4.34: Tests of within-subjects contrasts

Tests of Within-Subjects Contrasts							
Measure							
Source	time	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
time	Linear	1127.956	1	1127.956	2.899	.101	.100
	Quadratic	4755.453	1	4755.453	28.771	.000	.525
	Cubic	494.371	1	494.371	6.094	.020	.190

Table 4.35 shows that there is a significant quadratic trend indicating that during noon times the chances of sleepiness were lowest, in the morning could they were highest and in the late afternoon there was a slight rise. The cubic trend of SSS across time also reveals a significant result as the periods of the day appear to differ. The p-value = 0.020 and F-value = 6.094. Table 4.34 also provides the F- and p-values.

Table 4.35: Tests of between-subjects effects

Tests of Between-Subjects Effects						
Measure: Sleepiness						
Transformed Variable: Average						
Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Intercept	118628.484	1	118628.484	189.708	.000	.879
group	1551.385	1	1551.385	2.481	.127	.087
Error	16258.360	26	625.322			

Table 4.35 shows that there is not a significant difference between the Placebo and Active groups (F = 2.48, p-value = 0.127). A 95% confidence interval for the mean difference between Active and Placebo is (-9.93, 1.31), i.e. the degree of sleepiness between groups were comparable at week 3.

For the sake of comparison, all the group and week combinations are placed on one graph (Figure 4.12).

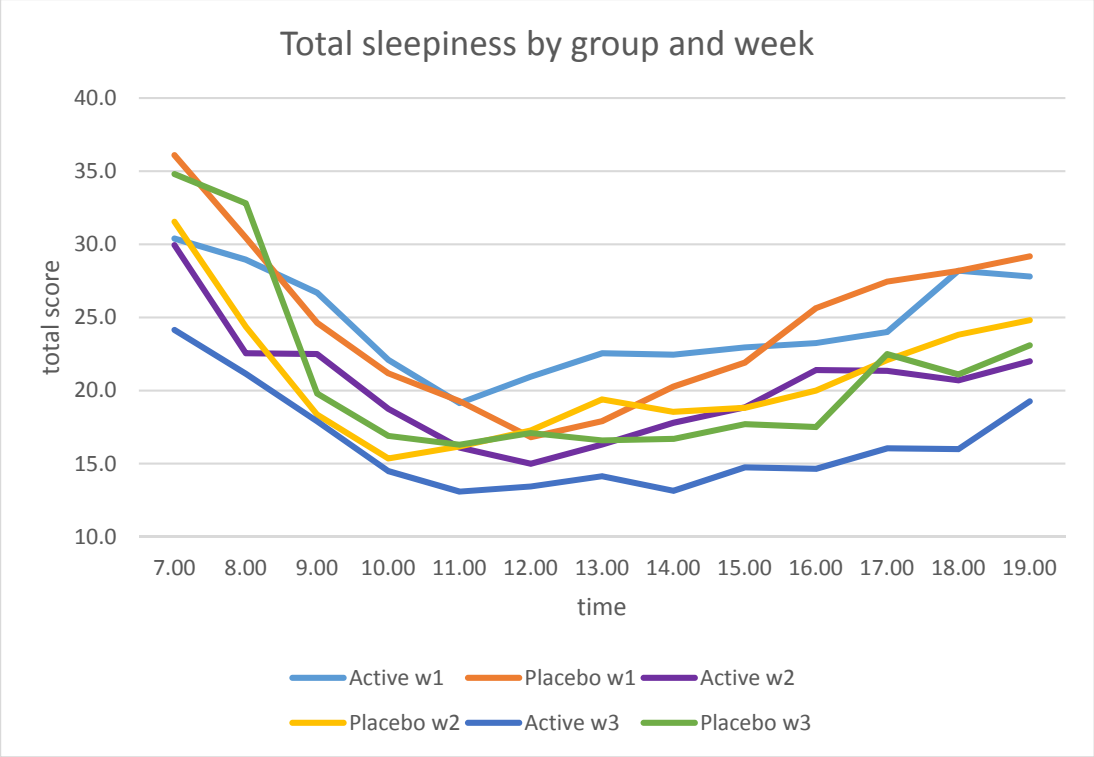

Figure 4.12: Comparison of mean SSS scores by hour per week and per group

A general trend can be observed with respect to the most sleepy and alert periods of the day which appear to differ significantly across the three weeks.

4.6 FINAL DISCUSSION

According to ESS data, participants in the Active group experienced significant improvement in their EDS when comparing week 1 with week 3 and week 2 with week 3 (before and after treatment); data from those in the Placebo group, however, also revealed similar improvements. Inter-group analysis confirmed that there was no statistically significant difference between the Active and Placebo groups suggesting that the improvements experienced were to a similar degree for both groups. However, when one compares the degree of improvement experienced within each group, the mean ESS Total scores reveal that the Active group improved by 40% and placebo group by only 30%.

Regarding SSS data, degrees of sleepiness were comparable between the two groups throughout the study i.e. no significant difference between mean SSS scores at weeks 1, 2 and 3.

4.7 SUMMARY OF REMEDIES PRESCRIBED

Various remedies were prescribed in 30CH potency (Table 4.36). Figure 4.13 shows the remedies grouped in accordance to their kingdoms (Animalia, Plantae and Mineral). The remedies were prescribed as per individual case analysis. All remedies were prescribed once on follow up consultation in a 25 ml amber glass bottle.

Animalia: Patients requiring the remedies of animal kingdom are intense, engaging, lively and animated (Reichenberg-Ullmann and Ullman, 2000). There are issues of survival, dominance and aggression versus submission sexuality and competitiveness. Their nature also includes impulsivity jealousy and mischief (Reichenberg-Ullmann and Ullman, 2000). The only remedy prescribed in the study coming from this kingdom was ***Lachesis muta*** (bushmaster snake/surukuku).

Plantae: This kingdom revolves around sensitivity and reactivity (Reichenberg-Ullmann and Ullman, 2000). There is a tendency to be more emotional rather than intellectual. Symptoms are mainly created by external factors. Remedies from this kingdom prescribed were ***Lycopodium clavatum, Pulsatilla, Cimicifuga racemosa*** and ***Nux vomica*****.**

Minerals: In this kingdom concerns centre on the structure of one's life. There appears to be a sense of order, organisation, responsibility and detail (Reichenberg-Ullmann and Ullman, 2000). Remedies from this kingdom prescribed were ***Phosphorus, Sulphur, Kalium carbonica, Calcarea carbonica, Natrum muriaticum*** and ***Silica terra*****.**

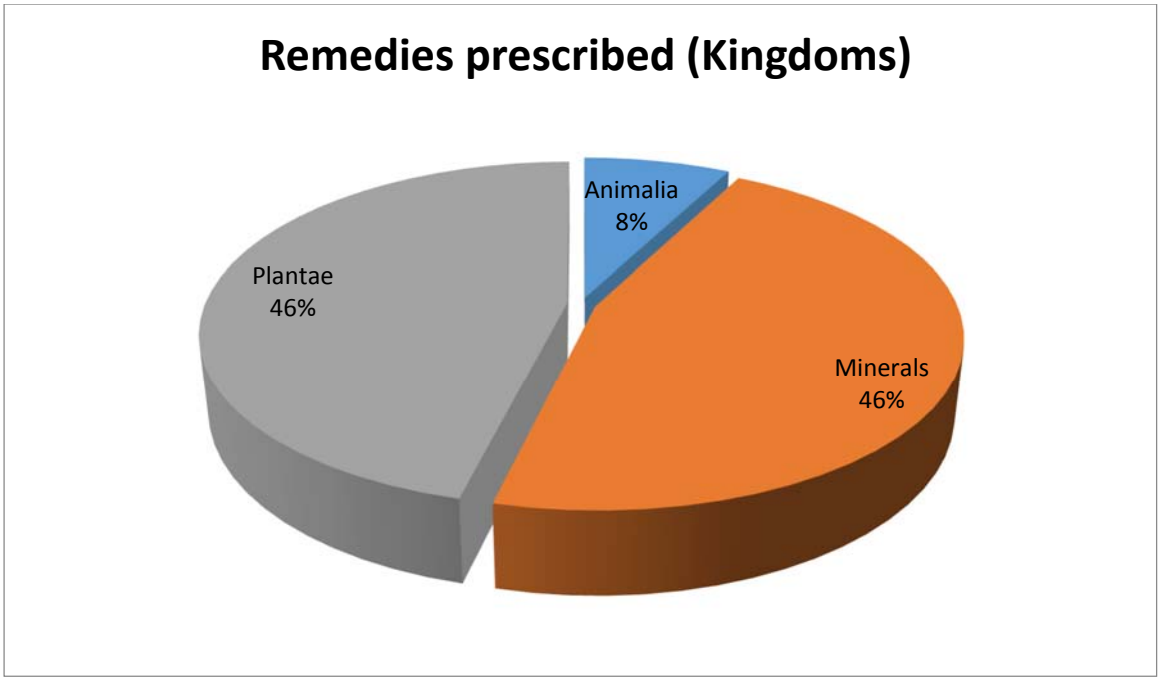

Figure 4.13: Percentages of remedies prescribed per kingdom

Table 4.36: Remedies prescribed in the study

Remedy name (30CH)	Frequency of prescription
1. *Natrum muriaticum*	9
2. *Phosphorus*	4
3. *Sulphur*	4
4. *Lycopodium clavatum*	2
5. *Lachesis muta*	2
6. *Thuja occidentalis*	1
7. *Silica terra*	1
8. *Pulsatilla*	1
9. *Nuv vomica*	1
10. *Kalium carbonica*	1
11. *Heleborus niger*	1
12. *Cimicifuga racemosa*	1
13. *Calcarea carbonica*	1

CHAPTER 5: DISCUSSION

The purpose of this double-blind placebo-controlled study was to determine the efficacy of the homoeopathic simillimum in the management of Excessive Daytime Sleepiness (EDS), by means of the Epworth Sleepiness Scale (Appendix C) and Stanford Sleepiness Scale (Appendix D).

5.1 DEMOGRAPHIC RESULTS

Participants were divided into two groups in y means of randomisation. Group 1 was the active group which consisted of 20 participants (64.5%) and group 2 was the placebo group which consisted of 11 participants (35.5%). In order to take part in the study, a participant had to receive a total ESS score of ≥ 10. Additionally, they were to meet the inclusion criteria found in the information letter (Appendix B).

5.1.1 Gender and age

Fatani *et al.* (2015) found that the prevalence of EDS in the Saudi population was higher among young (< 29 years) females (37.7%) than in males (22.1%). The convenient sample recruited in the current study comprised 48.4% females and 51.6% males which differs from the findings Fatani *et al.* (2015). However, the present study was experimental in design and not a prevalence study and had a smaller sample size which could explain the difference in prevalence according to gender. The range of age in total was between 18 to 28 years though the study was open to age groups between 18 to 30 years.

As stated in Chapter 2, although the demographic data represented a small sample, it does support the epidemiology of having more students suffering from EDS. Hence, the information gathered from the demographics could help provide a positive insight to the pattern of daytime sleepiness of the participants. As expected, the pattern of daytime sleepiness showed that females were most likely to experience daytime sleepiness when compared to the male population.

5.1.2 Ethnicity

Although the study was open to participants from any racial group, due to the racial demographic profile of university students being predominantly African, 100% of participants were African.

5.2 COMPARISON OF ACTIVE AND PLACEBO GROUPS

5.2.1 The application of the Epworth Sleepiness Scale

Data derived from the ESS in this study was able to demonstrate changes in EDS symptoms in response to treatment, a result which was also reported by Morrison and Riha (2012). The utility of ESS only quantifies the sleepiness, which measures the probability of dozing in eight common situations (Morrison and Riha, 2012).

5.2.1.1 The ESS mean scores

Significant changes in the total mean scores for both the placebo and active groups suggest an improvement from week 1 to week 3 (Table 4.13). This notwithstanding, the active group, however, appeared to have had a greater degree of improvement. For example, the mean total ESS scores for the Active group decreased by 5.75 points while that of the Placebo groups decreased by 4.64 points between consultation 2 and 3 with final mean total scores of 8.5 and 10.27, respectively. Overall, and as given in Figure 4.8, the Active group achieved a reduction in ESS Total score of 40% compared to a 31% reduction for the Placebo group measured over a 3-week period. Even though the results may have shown improvement in both groups by total mean scores, statistically, there was no significant difference between the groups.

Furthermore, the tests of within-subject analysis in Table 4.15 showed that there is no significant group effect ($F = 1.614$; $p = 0.214$) which strongly suggests that the average ESS Total scores do not differ for the placebo and active groups at baseline. More so and as further illustrated in Figure 4.8, the average ESS scores across time appear to be analogous.

In terms of the active group, the paired sample tests reveal a positive strong correlation ($r = 0.534$; $p < 0.05$) between week 1 and week 2 (Table 4.17). This suggests that the ESS score measured in week 1 (baseline) was similar to those measured for week 1

(first follow up consultation) which is to be expected as treatment commenced only after the first follow up consultation. On the contrary, no relationship was observed between week 2 and 3 as well as between week 1 and 3, respectively ($p > 0.05$), as there was no significant change in ESS scores over time in response to treatment.

On the other hand, and with regards to the placebo group, the strong positive relationship observed for the ESS Total scores for the three weeks (Table 4.20) suggests no differences in the daytime sleepiness ($p < 0.05$) over time. This means that the results measured were statistically similar and, therefore, participants' ESS scores did not improve over time. It can therefore be deduced that the placebo had no significant effect on the daytime sleepiness of the observed participants.

5.2.2 Application of the Stanford Sleepiness Scale

Besides the use of ESS scores to measure the participants' degree of sleepiness pre- and post-treatment, the SSS was also used in this study to gain understanding of the participants' sleepiness. The early reports of Johns (1991) suggested that SSS measures the feelings of sleepiness at a particular time. In line with his suggestion, each participant for a total of three weeks (21 days) completed the SSS scale on a daily basis for one week prior to commencing treatment (baseline data), followed by two weeks after commencing treatment. Participants rated their degree of sleepiness on an hourly basis throughout the wake period of the day using a 7-point Guttman scale (Bailes *et al.* 2006).

5.2.2.1 The SSS mean scores

Before the administration of the homoeopathic simillimum to the participants (week 1) in the Active group, the highest SSS baseline mean score (30.4) was measured in the morning (7:00am) while the lowest was scored at 11:00am (19.15) (Table 4.22). Similarly, and in respect to the placebo group, the highest (36.09) baseline mean score was recorded at 7:00am and the lowest at 12:00pm (16.81) (Table 4.23). Overall, the mean difference for the highest SSS baseline score measured for the active and placebo group was 5.69 while that measured for the lowest time interval score between the two groups was 2.69. As seen in Figure 4.9, it is worth mentioning that there was an intersection in certain times observed in both groups.

Furthermore, and in the first follow up consultation (week 2), it emerged that the highest mean score (29.95) for the active group (Table 4.26) was measured at 7:00am while the highest mean score (34.70) for the placebo group (Table 4.27). was measured at 10:00am. Figure 4.12 shows the quadratic trend and an intersection in sleepiness levels between both groups.

In week 3 (second follow up consultation), no significant difference between the active and placebo group in terms of the sleepiness was found ($p > 0.05$). However, the pattern of sleepiness significantly differed with time for both groups ($p < 0.05$). Overall, the trend analysis (Table 4.17 showed a systematic reduction in the sleepiness for the Active group when compared with week 1 and 2. In contrast, there were no visible differences in the Placebo group for week 1, 2 and 3. In light of these, it is sufficient to say that taking the homoeopathic simillimum, to some certain extent, did have an effect on the degree of sleepiness of the participants.

5.3 COMPARISON WITH OTHER STUDIES

Naudé, Couchman and Maharaj (2010) reported on a study on the effectiveness of the homoeopathic simillimum in a sleep related condition i.e. chronic primary insomnia. Therefore, that study formed the basis for comparison with the present study in order to establish the efficacy of homoeopathic simillimum as a therapeutic modality in the field of sleep related disorders.

Contrary to the findings of the present study, Naudé, Couchman and Maharaj (2010) determined the homoeopathic simillimum to be statistically superior to placebo in treating patients with chronic primary insomnia. The differences in the results observed in the present study and that of Naudé, Couchman and Maharaj (2010) may be attributed to the techniques of assessment, duration of the treatment as well as potency administered. For example, while ESS and SSS were both used in assessing the pattern of sleepiness in the present study, Naudé, Couchman and Maharaj (2010) used a Sleep Diary (SD) as well as the Sleep Insufficiency Index (SII). It is worth mentioning that the SD was a daily written record of individual's sleep-wake pattern that contained information and the SII was completed at each consultation.

With regards to the study duration, while the present EDS study duration was three weeks with two weeks of treatment, the study period in Naudé, Couchman and

Maharaj (2010) was six weeks, a significantly longer period, and participants were seen at two-week intervals. These differences in study duration could have had a significant effect on the outcome of the two studies, and a longer treatment period in the present study could have resulted in more significant results.

In terms of the homoeopathic prescription, the potency was standardised at 30CH in the present study. In contrast, in Naudé, Couchman and Maharaj's (2010) study, the treatment was prescribed in various potencies i.e. 30CH, 200CH, 1M, and 10M. The flexibility in potency range and the individualisation of the prescribed potency on a case-by-case basis is more congruent with the general homoeopathic practice setting; it is possible that limiting the present study to the 30CH potency may have limited therapeutic responses of the patients especially in deeper emotional cases which typically warrant a higher potency.

Drawing from the above comparison, it would be premature to assume that the homoeopathic simillimum was not significantly effective in reducing the excessive daytime sleepiness as reported in the present study as the factors mentioned above, if addressed in future studies, could result in a more favourable outcome. The previously mentioned differences observed between the present study and Naudé, Couchman and Maharaj's (2010) study could have contributed to the lack of differences observed between the active and placebo groups.

Importantly, a meta-analysis conducted by Mathie *et al.* (2014) of randomised placebo-controlled trials of individualised homoeopathic treatments revealed a statistically significant treatment effect of the individualised homoeopathic treatment. The review was conducted in order to monitor the rate of biases and model validity so as to obtain a single overall description per trial (high, moderate, low or very low quality). Interestingly, in the total of 32 reviewed randomised placebo-controlled trials (RCTs), the results revealed that three (3) trials were of high validity, eight (8) were of moderate validity, eighteen (18) of low quality and three (3) of very low quality. Therefore, it exceeded the condition-specific analysis (Mathie *et al*., 2014). The findings of the meta-analysis of the individualised homoeopathy treatment appeared to have a positive outcome when compared to placebo. Therefore, the current study does support the findings of the meta-analysis.

5.4 OVERALL IMPRESSION OF THE RESULTS

The placebo played a dynamic role in this study as it revealed a certain level of intrinsic effect. Placebo is defined as a substance that is pharmacologically inert, thus having no physiological action (Chauhan and Gupta, 2007). In this study, one can therefore establish what impact the placebo had.

Regarding homoeopathic prescriptions, most were from the commonly prescribed remedies. Each remedy was selected following proper case taking and physical examination. The researcher used the homoeopathic materia medica which seeks to find the remedy that fits the totality of symptoms of the participant, and homoeopathic repertory software (RADAR OPUS® version 24) was used to confirm the homoeopathic simillimum remedy by means of repertorisation. The initial case for each participant was repertorised by the researcher. The remedies chosen were based on the symptoms provided by the participants in conjunction with the observations of the researcher. The confirmation of the remedy was completed by the researcher and the clinician using the same software. The purpose of the repertory is to enable a homoeopathic practitioner or researcher to better review drugs known to have a therapeutic effect as studied in a given case (Vithoulkas, 1990).

The most commonly prescribed remedies in the study were as follows:

***Natrum muriaticum (Nat mur)*:**

Source: This remedy is made from **common salt (NaCl)**.

This mineral is one of the most abundant minerals that when used in excess can result in disturbance of the vital force. Since the research was about finding the simillimum for the management of EDS, there were many symptoms discovered during the case taking process. The cases that required *Nat mur* revealed symptoms such as headache and the desire to be alone which was a concomitant symptom in all the cases. The physical symptoms included a headache that started after prolonged sleeping hours. The headache was worse during heat, sunlight and exertion (exercise). Moreover, the physical symptoms included having unrefreshing sleep. The mind of a *Nat mur* case includes dreams of being chased and dreams of having conflict with a parent. The fear of rejection was mentioned in the cases. The emotional aspect included withdrawal after the manifestation of disappointment.

The sleeping patterns of this remedy include sobbing and/or talking during sleep, with dreams of robbers, thus resulting in feelings of weakness in the morning as confirmed during case taking. Worse times are between 9:00 to 11:00 mainly after exposure to the sun (Boericke, 2013).

Below are the some of the rubrics from the cases that revealed a moderate to higher grading thus leading to the prescription of this remedy.

Rubrics:

- Sleep- Unrefreshing (3)
- Eye- Pain- Burning (3)
- Eye- Pain- Stitching (2)
- Eye- Pain- Sand; as from (2)
- Head- Pain- Exertion- agg. (3)
- Head- Pain- Sleep-after- agg. (3)
- Generals- Food and drinks- Vegetables- Aversion (2)
- Generals- Food and drinks- Farinaceous foods- Desire (2)
- Mind- Absentminded (3)
- Mind- Fear- Robberies, of (3)
- Mind- Ailments from- Anger-Suppressed (2)
- Mind- Company- Aversion to (4)
- Mind- Dwells- Past disagreeable occurrences (4)
- Mind- Ailments from- Love, disappointed (4)
- Dreams- Robbers (3)

***Phosphorus*:**

Source: Phosphorus (the element)

Phosphorus is a mineral remedy that is abundant. Participants that required this remedy were showing general symptoms of hunger that was ravenous, desire to travel or to escape. They were experiencing symptoms of headaches in the vertex described as a burning sensation. Moreover, there were signs of insomnia at night. Symptoms were worse for heat and after eating. Furthermore, there was a concomitant of chest pains associated with anxiety located in the area of the heart.

Additionally, there were reports of internal heat causing the participants to be sleepless especially before midnight resulting in a sensation of sleep deprivation and sleepiness during the day. A number of these cases also experienced and reported short naps and frequent waking (Boericke, 2013).

Rubrics:

- Chest- Pain- Stitching pain (3)
- Chest- Anxiety in- Heart, region of (3)
- Female- Genitalia/sex- Menses- Offensive (2)
- General- Cold- agg. (2)
- Mouth- Speech- Stammering (2)
- Sleep- Light (2)
- Sleep- Sleepiness- Eating-after-agg (2)
- Stomach- Appetite- wanting (3)
- Stool- Mucus (2)

Sulphur:

Source: Flowers of Sulphur (The element)

Sulphur is another mineral that is abundantly available. Boericke (2013) explains that the symptoms of this remedy could be exacerbated by heat and be better for exertion. One of the interesting symptoms reported among participants was a fear of death as if the heart would stop. Excessive hunger was noticeable in this remedy as well as sleep that was unrefreshing. According to Boericke (2013), *Sulphur* cases typically comprise skin symptoms and the remedy is an important skin remedy, however interestingly skin eruptions was only reported by one case who received *Sulphur* as the simillimum. Symptoms of being pursued was detected through the dreams of participants.

According to Boericke (2013), *Sulphur* is periodically worse at 11:00am, their sleep tends to be unrefreshing and the cannot sleep between 2:00am to 5:00am. There is a sensation of drowsiness during daytime whereas at night one becomes wakeful (Boericke, 2013).

Rubrics:

- Dreams- Pursued- Being (2)
- Mind- Slowness (3)
- Mind- Fear- Death, of (3)
- Vertigo- Standing- agg. (2)
- Throat- Pain- Raw- as if (2)
- Chest- Pain- Sternum (2)
- Sleep- Light (2)
- Sleep- Sleepiness- Afternoon (2)
- Head- Pulsating pain (3)
- Generals- Food and drinks- Spices- Desires (3)
- Generals- Weariness (3)
- Generals- Cold- amel. (2)
- Eye- Heaviness- Lids (2)
- Skin- Eruptions- Red (3)
- Skin- Eruptions- Discharging (2)

Lycopodium clavatum:

Source: Wolf's foot; club moss

Based on the symptoms observed and obtained by the researcher, there was marked loss of concentration reported in these cases. Participants slept mostly during lectures thus venturing into "deep sleep", as they described it. There was a symptom of insomnia at night. During the daytime, sleepiness was worse after 2:00pm until 6:00pm. Before falling asleep, there was prolonged fatigue experienced by participants that required this remedy. The physical symptoms such as headaches were worse for noise and thirst and were better for sitting in a quiet place. The headaches were described as frontal headaches and were throbbing with a burning sensation at the back of the eyes. Participants disliked being the centre of attention.

According to Boericke (2013), the symptoms of *Lycopodium* are worse between 4:00pm to 8:00pm. There is drowsiness during the day especially on waking (Boericke, 2013).

Rubrics:

- Mind- Concentration- Difficult (3)
- Generals- Food and drink- Milk- agg. (2)
- Skin- Eruptions- Papular- Itching (2)

5.5 LIMITATIONS OF THE TRIAL

The limitations that emerged from this study include:

- The small sample size. A larger sample size may be required for future research in order to achieve better statistical results.
- Due to the chronicity of excessive daytime sleepiness in these participants an extension of the treatment period is desirable to improve results. However, time and financial constraints did not permit the extension of the study.
- The potency of the study was limited to 30CH, which may have affected the study's outcome. In future, flexibility in potency selection should be considered so that emotional cases receive a higher potency. Moreover, individualisation of potencies can be based on the case taken by the researcher.
- Unyielding consultation times. The researcher was allowed to see participants only during clinic hours (4 hours a day). This caused difficulty in scheduling consultations due to participants (who were all students) attending lectures. This simillimum study required the researcher to take a thorough case which required a consultation of at least 60 minutes in the consultation room with the participant. Therefore, the maximum number of participants the researcher could see per clinical session was three. Future studies require more flexible contact time with patients and this should be arranged according to what suits them as well as the researcher/clinic schedule.

CHAPTER 6: CONCLUSION

This study aimed to determine the efficacy of the homoeopathic simillimum in the management of excessive daytime sleepiness. Thirty-one students that met the inclusion criteria, with ESS scores ≥ 10, were recruited for the study and were randomly assigned into two groups. Group 1 (n = 20) received a homoeopathic simillimum while group 2 (n = 11) received a placebo. The efficacy of the homoeopathic simillimum was determined by the patients' perception of the treatment using two validated tools namely the ESS and the SSS. Each participant was prescribed their respective individualised homoeopathic simillimum or placebo at the first follow up consultation (to be taken for two weeks), based on the totality of symptoms derived from the homoeopathic consultation. The researcher recorded findings of each consultation as a conceivably unbiased evaluation for management of EDS.

Regarding the ESS data, the results indicated that both groups experienced an overall improvement in EDS symptoms at the completion of the study as the means were comparable at the completion of the study; although the active group experienced a higher reduction in mean ESS scores compared to the placebo (40% and 31% respectively). This did not reach statistical significance despite the perceived improvement in the participants' sleepiness. The alternate hypothesis was rejected as the multivariate repeated measures analysis failed to show any significant difference between the two groups beyond the 0.05 confidence interval ($p > 0.05$).

Regarding the SSS data, the repeated measures ANOVA method failed to show a significant difference between the placebo and active groups ($p > 0.05$). In particular, it emerged that the pattern of peak sleepiness at 7:00am remained the same in both the active and placebo groups throughout the study. Nevertheless, changes in sleepiness were notable during daytime, perhaps due to a positive effect perceived by participants after taking the treatment. Moreover, effects on the active group showed a positive outcome after analysis of the results when compared to the placebo group.

6.1 BENEFITS OF THE STUDY

While homoeopathy in recent years has gained significant recognition worldwide, the knowledge about homoeopathy appears to be limited South Africa. The present study has therefore aided in bridging the knowledge gap regarding homoeopathy by bringing to the forefront alternative treatment for improving the degree of daytime sleepiness. More so, participants have had the opportunity to discuss and interact with the researcher during the period of consultation thereby improving their rudimentary understanding of homoeopathy.

Equally significant, during the consultation period participants will have received further insight into EDS and its implications. During such consultation participants were properly educated on why their individual sleep hygiene may trigger EDS's condition. The knowledge gained from participating in the study may enable the participants to make a change regarding their lifestyle.

6.2 RECOMMENDATIONS

Within the limitation of the present study, the following recommendations are proposed:

- Flexibility of potencies to provide proper treatment for emotional cases as they may require higher potencies. This flexibility will allow the researcher to individualise the potency on a case-by-case basis and prescribe higher potencies for heavily weighted emotional cases.
- Forthcoming studies should strive for a wider variety of participants with respect to ethnicity as this variable may influence the degree or experience of EDS amongst students.
- For improved accessibility to participants, the usage of facilities outside of DUT should be permitted or considered.
- An increase in the number of participants to achieve greater statistical results.
- The duration of the study should be extended to at least six months as the researcher recognises that excessive daytime sleepiness is a chronic condition and possibly more favourable results could be obtained if data collection continued for a longer period.

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APPENDICES

APPENDIX A: ADVERTISEMENT

DUT DURBAN UNIVERSITY OF TECHNOLOGY

FACULTY OF HEALTH SCIENCES

Sleepy during the day?

Are you a student suffering from Excessive Daytime

Sleepiness?

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

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

Ntombizethu Mbatha 081 8348 155

The homoeopathic clinic 031 373 2041

APPENDIX B: INFORMATION LETTER AND CONSENT FORM

LETTER OF INFORMATION

Title of the Research Study: The efficacy of the homoeopathic similimum in the management of excessive daytime sleepiness.

Principal Investigator/s/researcher: (Ntombizethu Annie Mbatha, 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 an 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.

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 medicine (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 following 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: Ntombizethu Annie Mbatha

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.

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**

_____ _____ _____

Full Name of Legal Guardian (If applicable) **Date** **Signature**

APPENDIX C: STANFORD SLEEPINESS SCALE

Stanford Sleepiness Scale

"Alertness Test"

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 dream-like 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 nights rest could improve your level of alertness and day to day performance.

APPENDIX D: 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	

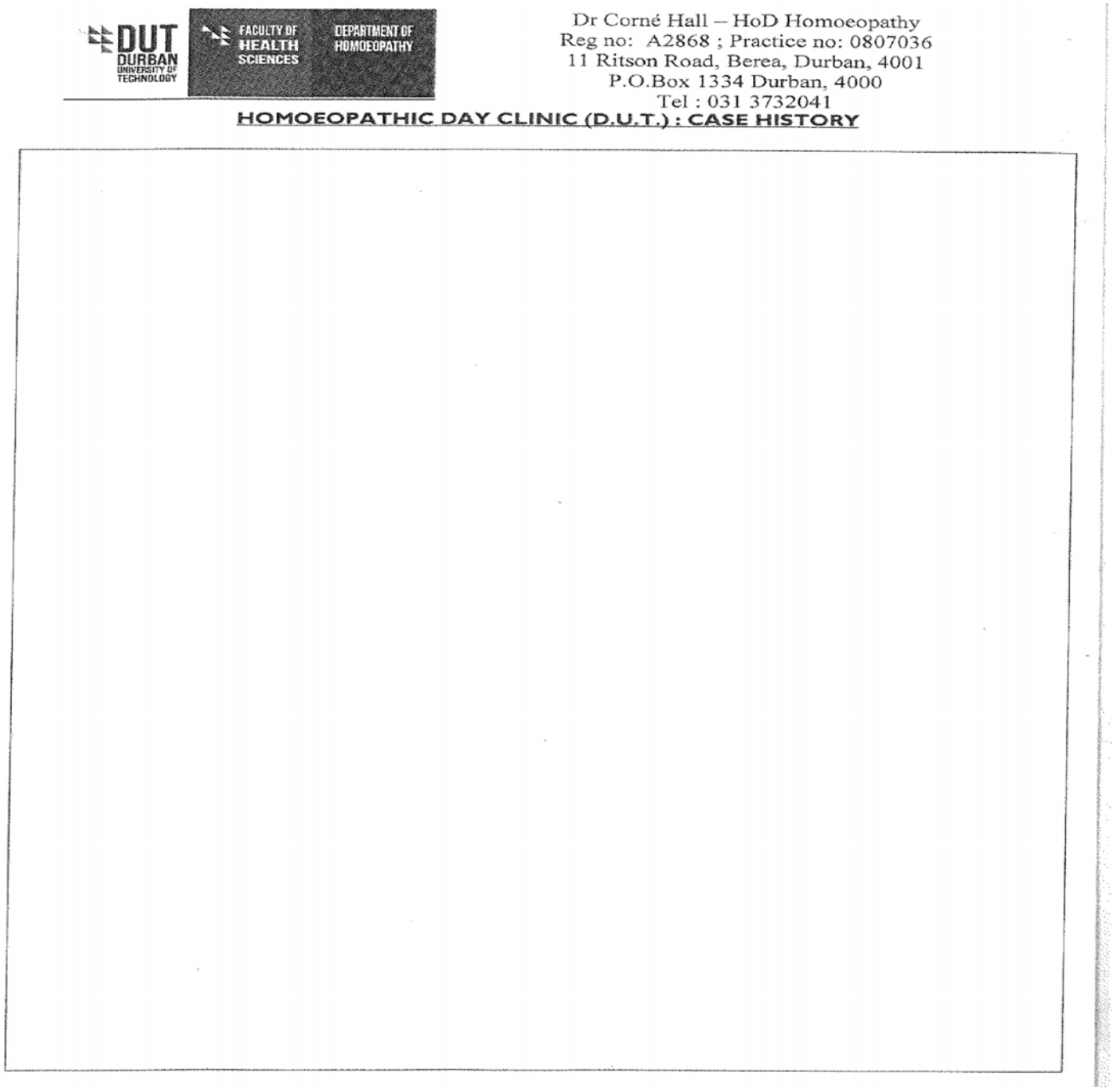
SCORE RESULTS:

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

DUT DURBAN UNIVERSITY OF TECHNOLOGY
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HOMOEOPATHIC DAY CLINIC (D.U.T.) : CASE HISTORY

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11 Ritson Road, Berea, Durban, 4001
P.O.Box 1334 Durban, 4000
Tel : 031 3732041

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

Student signature	**Date**
Clinician Signature	**Date**

APPENDIX F: SOAPE NOTE AND PRESCRIPTION RECORD

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/Ø**
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: 8 January 2016

Name of Student: NTOMBIZETHU MBATHA

Student number: 21001842

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

Item	**Quantity**	**Unit Price**	**Total**
50ml Amber glass bottles	15	R8.00	R120
Packets	45	R0.50	R22.50
Alcohol 20%	750ml	R 10/100ml	R75
30 plussed potencies	35	R35	1225
TOTAL AMOUNT DUE			R 1442.50

*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.

Ref: Research Quote

APPENDIX H: APPLICATION LETTER FOR UTILITY OF HOMEOPATHIC DAY CLINIC

Ms NA Mbatha

D 1954 Sangwana road

KwaMashu

4359

Cell: 0818348155

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 *Ntombizethu Mbatha* 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 the homoeopathic similimum in the management of excessive daytime sleepiness.

Purpose of the study

The aim of this randomised, double-blind placebo controlled study is to determine the efficacy of the homoeopathic similimum in the management of EDS in terms of the Epworth Sleepiness Scale (Johns, 1991) and Stanford Sleepiness Scale (Hoddes et al. 1973).

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

Ntombizethu Annie Mbatha

Student No: **21001842**

mbathana@gmail.com

APPENDIX I: RECRUITMENT APPLICATION LETTER

Ms NA Mbatha

D 1954 Sangwana road PO

KwaMashu

4359

Cell: 0818348155

8 February 2016

Professor S. Moyo

Director of Research - DUT

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

I *Ntombizethu Annie Mbatha* 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 the homoeopathic similimum in the management of excessive daytime sleepiness.

Purpose of the study

The aim of this randomised, double-blind placebo controlled study is to determine the efficacy of the homoeopathic similimum in the management of EDS in terms of the Epworth Sleepiness Scale (Johns, 1991) and Stanford Sleepiness Scale (Hoddes et al. 1973).

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

Ntombizethu Annie Mbatha

Student No: **21001842**

mbathana@gmail.com

APPENDIX J: A GUIDE TO MAKING A REMEDY SOLUTION

Hahnemann's Water Potencies

- How to make a **REMEDY SOLUTION BOTTLE:** 30CH plussed potency.

Fill a clean amber bottle with distilled water or purified water (no tap water except in emergency).

18ml, dropper bottle to 25ml bottle may be used

ADD 2ml of 96% PURE ETHYL ALCOHOL (190 PROOF EVERCLEAR). Not methyl or rubbing alcohol! If everclear is not available, use the highest proof, least smelly and colourless if possible. When storing the solution, at least 20% alcohol is necessary. The longer the solution is stored, the greater the amount of alcohol is needed.

PUT ONE DOSE of the indicated remedy into the bottle and dissolve.

In a plussed CH potency, 1 dose= twelve to fifteen #10 poppy seed size pellets or one or 2 #35 size pellet or two drops of liquid.

- **SUCCUSSING THE REMEDY SOLUTION BOTTLE:** For one succusion, hold the bottle in your right hand and strike the bottom of the bottle smartly against the palm of the left hand (or soft bound leather book) from a distance of nearly 2 feet. This changes the potency of the dose slightly so that the body accepts it more readily with less aggravation working faster, deeper and with a more gentle effect. Succuss 8-10 times before each dose.
- **HOW TO MAKE A DOSAGE CUP:** For a plussed potency use 4 drops from the dropper bottle into 15ml of water and stir vigorously.
- **DOSAGE AMOUNTS:** 1 teaspoon, 1-3 times daily taken directly from the 25ml remedy solution bottle. If using a small dropper, 4 drops as 1 dose may be used.
- **DOSE ADJUSTMENTS**: If a strong reaction occurs, adjust the dose:
    1. Take a remedy less often.
    2. Succuss the remedy solution bottle two times
    3. Use more water
    4. Use the 2nd, 3rd, or more dosage cups SENSITIVE PERSONS: use a larger amount of water (25ml) in the remedy solution bottle with one #10 pellet. Succuss the remedy bottle 2 times, take 1 teaspoon of this solution and put it in a cup filled with 25ml of distilled water, stir vigorously. Take ½ teaspoon of this first dilution. You make as many dosage cups as needed. Take one dose 1 or 2 times a week, slowly increase frequency if needed.
- **DOSE REPETITION: ACUTE**: Dose may be 1-3 times daily of 30CH, Most effective in water solution, with succussions in between each dose. Adjust as needed. CHRONIC: teaspoon 1-3 times daily, direct from a remedy solution bottle, or with a dosage cup. You may also take 2-4 drops from a dropper bottle. Always adjust as needed, either more or less. Don't forget to succuss before each dose.
- If a 25ml dropper bottle is not available:
    1. Fill a disposable plastic or paper cup with 15ml of water (distilled water if available).
    2. Put 1 dose of remedy in water. For plussed potency, 1 dose= twelve to fifteen #10 poppy seed size pellets or one or two #35 size pellet or two to four drops of liquid
    3. Stir vigorously with a disposable plastic spoon or stick. You may keep the cup and stirrer to be used again for the same remedy in the same potency.
    4. 1 teaspoon of this solution is one dose.
    5. A new solution in fresh water should be prepared every time a dose is needed.

REFERENCE

Murphy, R. 2006. Hahnemann's LM and Water Potencies (online). Available: http://www.alchemilla.com/index.php/homeopathic-medicine-mainmenu-33/14-hahnemanns-lm-and-water-potencies-2006-01-22. (Accessed 2016-03-03).

APPENDIX K: RECRUITMENT APPLICATION LETTER TO OTHER UNIVERSITY STUDENTS

Ms NA Mbatha

D 1954 Sangwana road PO

KwaMashu

4359

Cell: 0818348155

25 July 2016

To whom it may concern

Director of Research

Re: Permission to recruit UKZN/MUT students for M.Tech: Homoeopathy research

I *Ntombizethu Annie Mbatha* currently registered for M.Tech qualification at Durban University of Technology: Homoeopathy department am kindly requesting permission to advertise and recruit UKZN/MUT 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 the homoeopathic similimum in the management of excessive daytime sleepiness.

Purpose of the study

The aim of this randomised, double-blind placebo controlled study is to determine the efficacy of the homoeopathic similimum in the management of EDS in terms of the Epworth Sleepiness Scale (Johns, 1991) and Stanford Sleepiness Scale (Hoddes et al. 1973).

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

Ntombizethu Annie Mbatha

Student No: **21001842**

mbathana@gmail.com

APPENDIX L: ETHICAL CLEARANCE LETTER

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
http://www.dut.ac.za/research/institutional_research_ethics

www.dut.ac.za

11 October 2016

IREC Reference Number: **REC 71/16**

Ms N A Mbatha
D 1954
Sangwana Road
P O KwaMashu
4359

Dear Ms Mbatha

The efficacy of the homoeopathic similimum in the management of excessive daytime sleepiness

I am pleased to inform you that Provisional Approval has been granted to your proposal REC 71/16 subject to:

- Obtaining and submitting the necessary gatekeeper permission/s to the IREC.

Full approval is subject to meeting the above condition.

The Proposal has been allocated the following Ethical Clearance number **IREC 105/16**. 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 IREC 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 IREC SOP's.

Yours Sincerely

Professor J K Adam
Chairperson: IREC

APPENDIX M: PERMISSION TO CONDUCT RESEARCH AT DUT

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

25th October 2016

Ms Ntombizethu Annie Mbatha
c/o Department of Homeopathy
Faculty of Health Sciences
Durban University of Technology

Dear Ms Mbatha

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 the homoeopathic similimum in the management of excessive daytime sleepiness" at the Durban University of Technology.

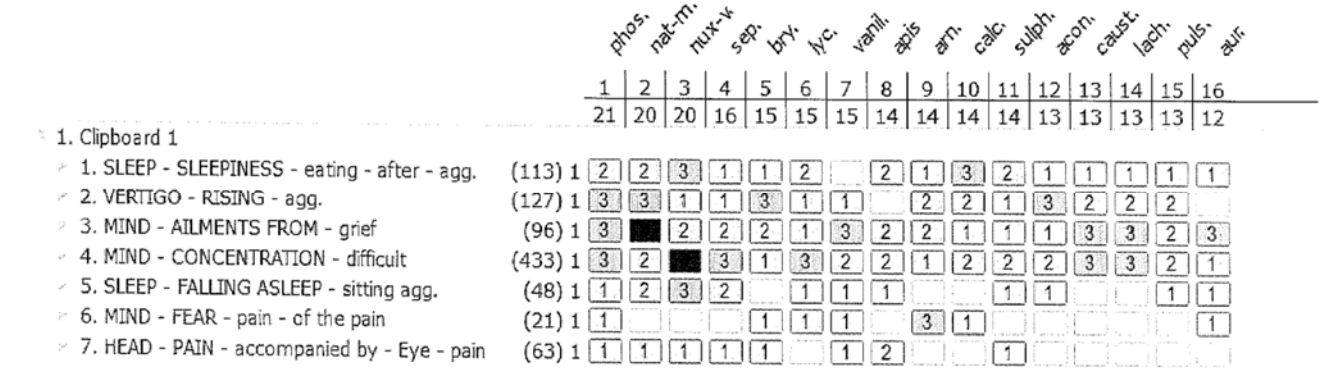
We would be grateful if a summary of your key research findings can be submitted to the IRC on completion of your studies.

Kindest regards.
Yours sincerely

APPENDIX N: REPERTORISATION CHARTS FOR SIMILLIMUM GROUP

REPERTORISATION CHART I

01

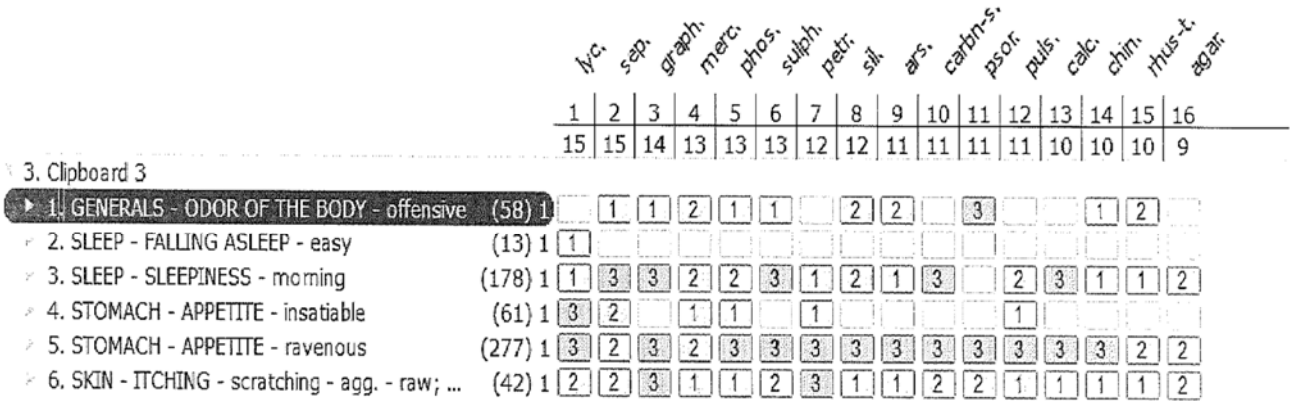


		phos.	nat-m.	nux-v	sep.	bry.	lyc.	vanil.	apis	arn.	calc.	sulph.	acon.	caust.	lach.	puls.	aur.
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
		21	20	20	16	15	15	15	14	14	14	14	13	13	13	13	12
1. Clipboard 1																	
1. SLEEP - SLEEPINESS - eating - after - agg.	(113) 1	2	2	3	1	1	2		2	1	3	2	1	1	1	1	1
2. VERTIGO - RISING - agg.	(127) 1	3	3	1	1	3	1	1		2	2	1	3	2	2	2	
3. MIND - AILMENTS FROM - grief	(96) 1	3		2	2	2	1	3	2	2	1	1	1	3	3	2	3
4. MIND - CONCENTRATION - difficult	(433) 1	3	2		3	1	3	2	2	1	2	2	2	3	3	2	1
5. SLEEP - FALLING ASLEEP - sitting agg.	(48) 1	1	2	3	2		1	1	1			1	1			1	1
6. MIND - FEAR - pain - of the pain	(21) 1	1				1	1	1		3	1						1
7. HEAD - PAIN - accompanied by - Eye - pain	(63) 1	1	1	1	1	1		1	2			1					

REPERTORISATION CHART II

		calc.	nux-v	lyc.	sil.	sulph.	alum.	ars.	bry.	caust.	con.	kali-c.	nat-m.	phos.	puls.	sep.	agar.
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
		17	16	15	14	14	13	13	13	13	13	13	13	13	13	13	12
2. Clipboard 2																	
1. SLEEP - SLEEPINESS - eating - after - agg.	(113) 1	3	3	2	2	2		1	1	1	1	2	2	2	1	1	3
2. SLEEP - SLEEPLESSNESS - riding - carriage; ...	(3) 1	2					2										
3. RECTUM - CONSTIPATION	(528) 1	3	3	3	3	3	3	3	3	3	3	2	3	3	2	3	2
4. GENERALS - SEASONS - winter - agg.	(102) 1	2	3	3	2	2	2	3	3	2	2	3	1	2	3	2	2
5. RECTUM - CONSTIPATION - ineffectual urgin...	(256) 1	2	3	3	3	3	2	2	2	3	3	2	3	2	3	3	1

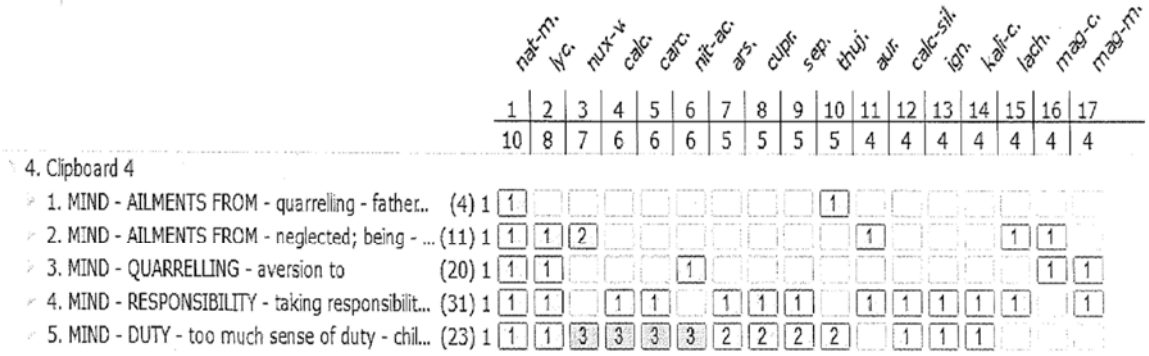
REPERTORISATION CHART III



		lyc.	sep.	graph.	merc.	phos.	sulph.	petr.	sil.	ars.	carbn-s.	psor.	puls.	calc.	chin.	rhus-t.	agar.
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
		15	15	14	13	13	13	12	12	11	11	11	11	10	10	10	9
3. Clipboard 3																	
1. GENERALS - ODOR OF THE BODY - offensive	(58) 1		1	1	2	1	1		2	2		3			1	2	
2. SLEEP - FALLING ASLEEP - easy	(13) 1	1															
3. SLEEP - SLEEPINESS - morning	(178) 1	1	3	3	2	2	3	1	2	1	3		2	3	1	1	2
4. STOMACH - APPETITE - insatiable	(61) 1	3	2		1	1		1					1				
5. STOMACH - APPETITE - ravenous	(277) 1	3	2	3	2	3	3	3	3	3	3	3	3	3	3	2	2
6. SKIN - ITCHING - scratching - agg. - raw; ...	(42) 1	2	2	3	1	1	2	3	1	1	2	2	1	1	1	1	2

REPERTORISATION CHART IV

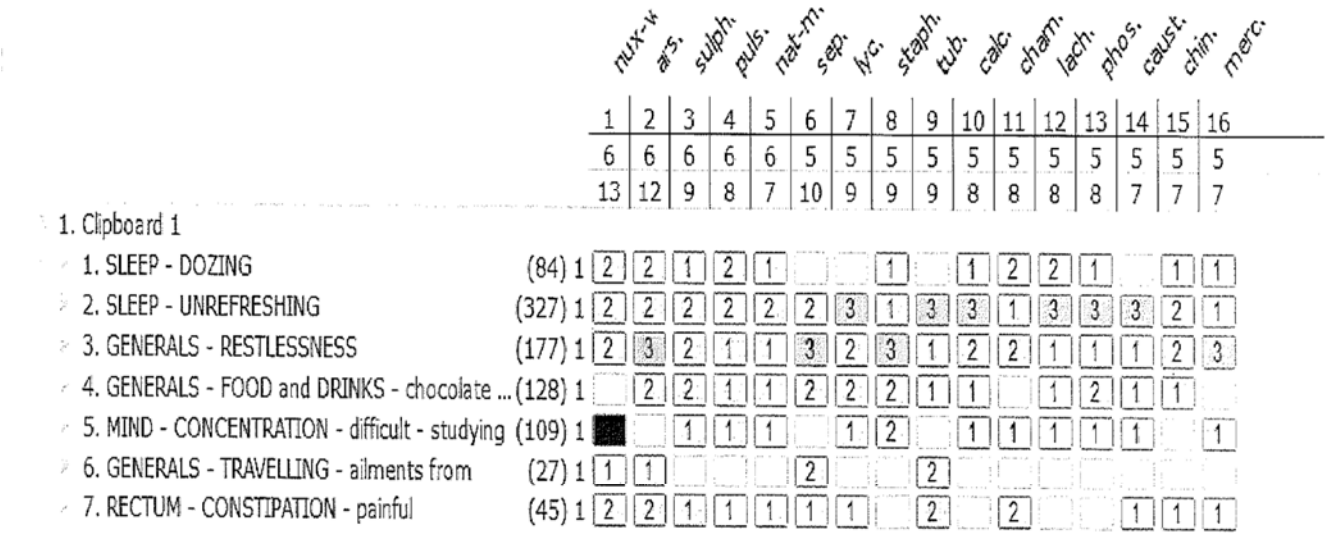
09



		nat-m.	lyc.	nux-v.	calc.	carc.	nit-ac.	ars.	cupr.	sep.	thuj.	aur.	calc-sil.	ign.	kali-c.	lach.	mag-c.	mag-m.
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
		10	8	7	6	6	6	5	5	5	5	4	4	4	4	4	4	4
4. Clipboard 4																		
1. MIND - AILMENTS FROM - quarrelling - father...	(4) 1	1									1							
2. MIND - AILMENTS FROM - neglected; being - ...	(11) 1	1	1	2								1				1	1	
3. MIND - QUARRELLING - aversion to	(20) 1	1	1				1										1	1
4. MIND - RESPONSIBILITY - taking responsibilit...	(31) 1	1	1		1	1		1	1	1		1	1	1	1	1		1
5. MIND - DUTY - too much sense of duty - chil...	(23) 1	1	1	3	3	3	3	2	2	2	2		1	1	1			

REPERTORISATION CHART V

05 (07/11/2016).



		nux-v	ars.	sulph.	puls.	nat-m.	sep.	lyc.	staph.	tub.	calc.	cham.	lach.	phos.	caust.	chin.	merc.
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
		6	6	6	6	6	5	5	5	5	5	5	5	5	5	5	5
		13	12	9	8	7	10	9	9	9	8	8	8	8	7	7	7
1. Clipboard 1																	
1. SLEEP - DOZING	(84) 1	2	2	1	2	1			1		1	2	2	1		1	1
2. SLEEP - UNREFRESHING	(327) 1	2	2	2	2	2	2	3	1	3	3	1	3	3	3	2	1
3. GENERALS - RESTLESSNESS	(177) 1	2	3	2	1	1	3	2	3	1	2	2	1	1	1	2	3
4. GENERALS - FOOD and DRINKS - chocolate ...	(128) 1		2	2	1	1	2	2	2	1	1		1	2	1	1	
5. MIND - CONCENTRATION - difficult - studying	(109) 1			1	1	1		1	2		1	1	1	1	1		1
6. GENERALS - TRAVELLING - ailments from	(27) 1	1	1				2			2							
7. RECTUM - CONSTIPATION - painful	(45) 1	2	2	1	1	1	1	1		2		2			1	1	1

REPERTORISATION CHART VI

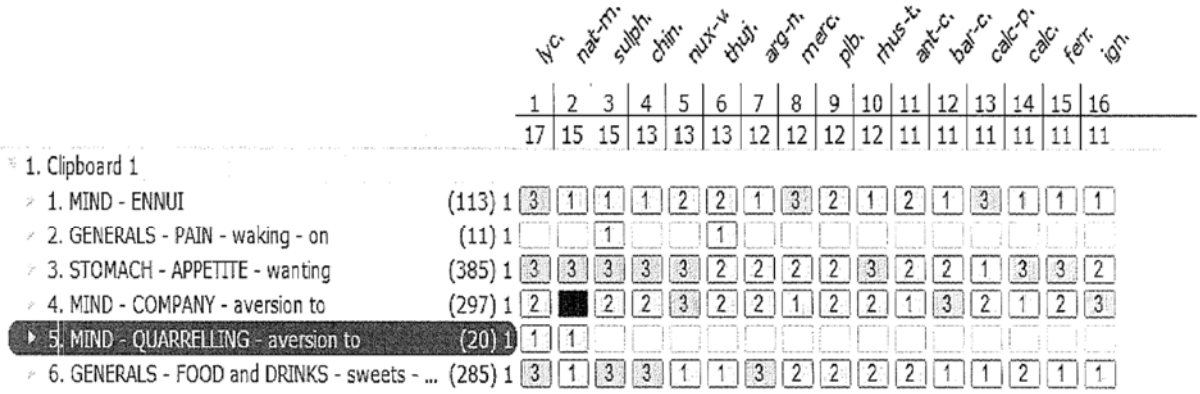
06

6. Clipboard 6
- 1. SLEEP - FALLING ASLEEP - easy
- 2. SLEEP - SLEEPINESS - afternoon
- 3. MIND - RESERVED
- 4. MIND - HIDING - himself
- 5. MIND - SECRETIVE

	ign.	lyc.	sal-fl.	bell.	nat-m.	staph.	hyos.	lach.	phos.	sep.	spong.	thuj.	aur.	bar-c.	nux-v	ratt-norv-s.
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
	17	17	15	14	14	14	13	13	13	13	13	13	12	12	12	12
(13) 1		1														
(233) 1	1	1	1	1	1	2	1	2	2	1	2	1	1		3	
(135) 1	2	1	1	1	3	2	2	1	3	1	1	1	1		1	
(50) 1	2	1	1	3	1	1	1	1			1		1	2		2
(45) 3	2	2	2	1	1	1	1	1	1	2	1	2	1	2	1	2

REPERTORISATION CHART VII

07



		lyc.	nat-m.	sulph.	chin.	nux-v.	thuj.	arg-n.	merc.	plb.	rhus-t.	ant-c.	bar-c.	calc-p.	calc.	fer.	ign.
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
		17	15	15	13	13	13	12	12	12	12	11	11	11	11	11	11
1. Clipboard 1																	
1. MIND - ENNUI	(113) 1	3	1	1	1	2	2	1	3	2	1	2	1	3	1	1	1
2. GENERALS - PAIN - waking - on	(11) 1			1			1										
3. STOMACH - APPETITE - wanting	(385) 1	3	3	3	3	3	2	2	2	2	3	2	2	1	3	3	2
4. MIND - COMPANY - aversion to	(297) 1	2		2	2	3	2	2	1	2	2	1	3	2	1	2	3
5. MIND - QUARRELLING - aversion to	(20) 1	1	1														
6. GENERALS - FOOD and DRINKS - sweets - ...	(285) 1	3	1	3	3	1	1	3	2	2	2	2	1	1	2	1	1

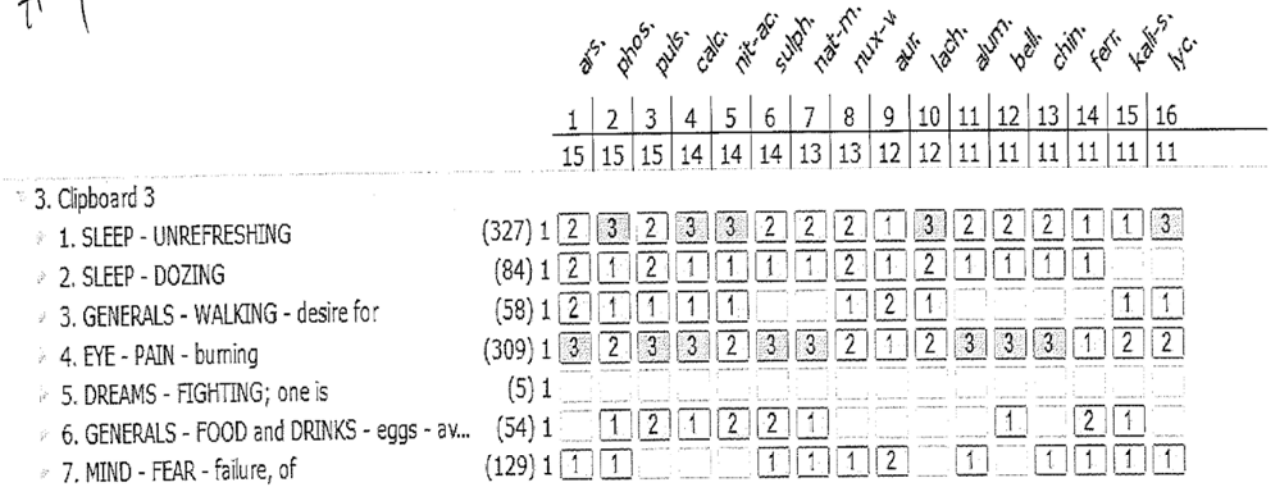
REPERTORISATION CHART VIII

8.

		nat-m.	puls.	apis	bell.	chin.	ars.	cocc.	rhus-t.	ign.	kali-c.	nux-v.	staph.	sulph.	calc.	graph.	lach.
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
		20	20	19	19	18	17	17	17	16	16	16	16	16	15	15	15
2. Clipboard 2																	
1. EYE - OPEN lids - sleep; during	(31) 1		1	1	2	1	1	2						1	1		
2. SLEEP - DOZING	(84) 1	1	2	3	1	1	2	2	1	1	1	2	1	1	1	1	2
3. GENERALS - ANEMIA	(263) 1	3	3	2	2	3	3	1	2	2	3	2	3	3	3	3	2
4. HEAD - PAIN - dull pain	(296) 1	1	3	2	1	2	1	2	2	1	1	3	1	1	1	2	2
5. HEAD - PAIN - heat - during	(97) 1	3	2	3	3	3	2	2	2	2	1	2	1	1	1	1	2
6. HEAD - PAIN - bending - head - forward - a...	(23) 1	1			1				2								
7. FEMALE GENITALIA/SEX - MENSES - absent	(212) 1	2	3	2	2	2	2	2	2	2	3	2	2	3	2	3	2
8. MIND - FEAR - rejection; of	(12) 1	2								2	1		2				

REPERTORISATION CHART IX

#9



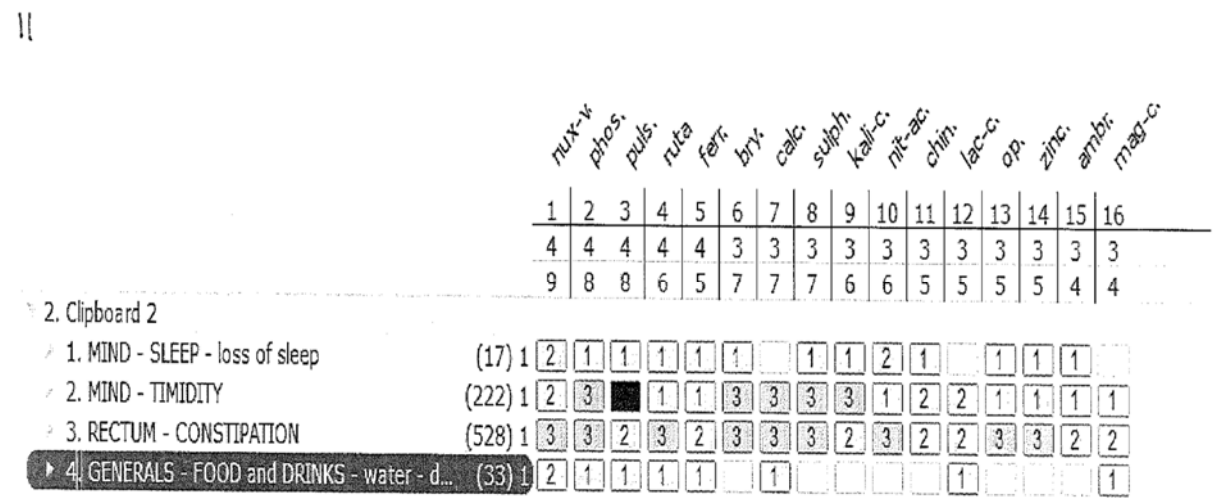
		ars.	phos.	puls.	calc.	nit-ac.	sulph.	nat-m.	nux-v.	aur.	lach.	alum.	bell.	chin.	fer.	kali-s.	lyc.
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
		15	15	15	14	14	14	13	13	12	12	11	11	11	11	11	11
3. Clipboard 3																	
1. SLEEP - UNREFRESHING	(327) 1	2	3	2	3	3	2	2	2	1	3	2	2	2	1	1	3
2. SLEEP - DOZING	(84) 1	2	1	2	1	1	1	1	2	1	2	1	1	1	1		
3. GENERALS - WALKING - desire for	(58) 1	2	1	1	1	1			1	2	1					1	1
4. EYE - PAIN - burning	(309) 1	3	2	3	3	2	3	3	2	1	2	3	3	3	1	2	2
5. DREAMS - FIGHTING; one is	(5) 1																
6. GENERALS - FOOD and DRINKS - eggs - av...	(54) 1		1	2	1	2	2	1					1		2	1	
7. MIND - FEAR - failure, of	(129) 1	1	1				1	1	1	2		1		1	1	1	1

REPERTORISATION CHART X

10

		lyc.	calc.	nat-m.	sulph.	bry.	sil.	ars.	graph.	nux-v	phos.	op.	puls.	acon.	calad.	chin.	cocc.
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
		22	18	18	18	17	17	16	15	15	14	13	13	12	12	12	12
4. Clipboard 4																	
1. SLEEP - SLEEPLESSNESS - night	(312) 1	3	3	2	2	1	2	2	2	2	2	2	3	2	2	2	1
2. MIND - CONFUSION of mind - sleepiness; w...	(5) 1																
3. SLEEP - LIGHT	(130) 1	2	2	1	2	3	2	2	2	2	1	2	1	2	1	2	1
4. SLEEP - UNREFRESHING - morning	(38) 1	2		2	3	1	1		2	2		1					2
5. CHEST - PAIN - inspiration - agg. - stitching ...	(68) 1	2	2	3	1	3	2	2			2	1		3			
6. STOMACH - APPETITE - ravenous	(277) 1	3	3	3	3	2	3	3	3	3	3	2	3	1	1	3	2
7. GENERALS - FOOD and DRINKS - dry food -...	(19) 1	2	3		1	1	1			1			2		1	1	
8. GENERALS - FOOD and DRINKS - drinks - d...	(34) 1	1		1				2	1		1				2		1

REPERTORISATION CHART XI



		nux-v.	phos.	puls.	ruta	fer.	bry.	calc.	sulph.	kali-c.	nit-ac.	chin.	lac-c.	op.	zinc.	ambr.	mag-c.
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
		4	4	4	4	4	3	3	3	3	3	3	3	3	3	3	3
		9	8	8	6	5	7	7	7	6	6	5	5	5	5	4	4
2. Clipboard 2																	
1. MIND - SLEEP - loss of sleep	(17) 1	2	1	1	1	1	1		1	1	2	1		1	1	1	
2. MIND - TIMIDITY	(222) 1	2	3	■	1	1	3	3	3	3	1	2	2	1	1	1	1
3. RECTUM - CONSTIPATION	(528) 1	3	3	2	3	2	3	3	3	2	3	2	2	3	3	2	2
4. GENERALS - FOOD and DRINKS - water - d...	(33) 1	2	1	1	1	1		1					1				1

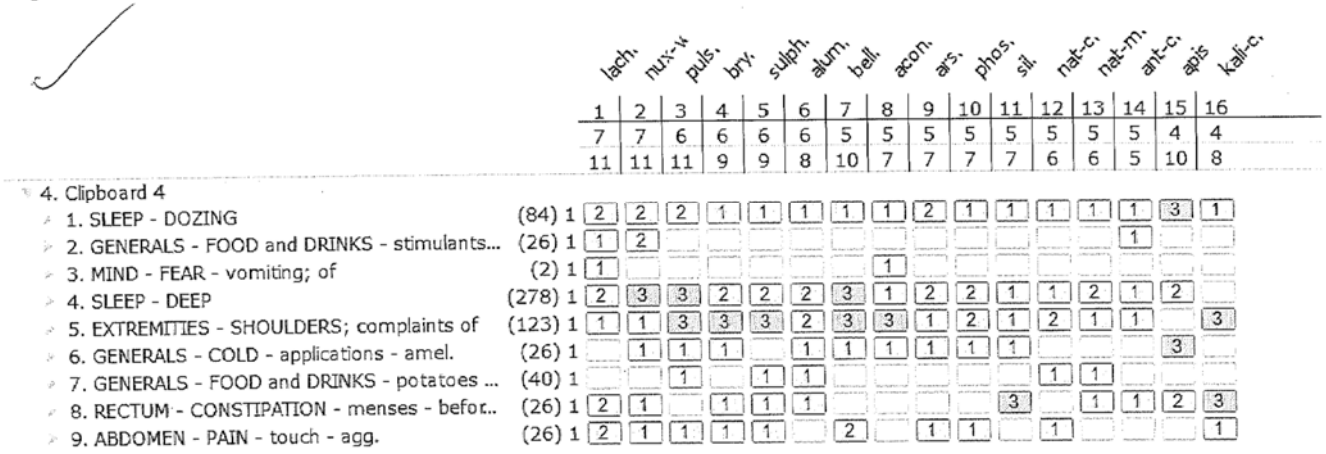
REPERTORISATION CHART XII

12

		hell.	phos.	kali-p.	lyc.	nat-m.	sulph.	bell.	calc.	kali-s.	carc.	nux-v.	ars.	cham.	merc.	ign.	mag-c.
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
		4	4	4	4	4	4	4	4	4	4	3	3	3	3	3	3
		9	7	6	6	6	6	5	5	5	4	7	6	6	6	5	5
3. Clipboard 3																	
1. SLEEP - UNREFRESHING - morning	(38) 1			1	2	2	3			1		2					2
2. MIND - CONCENTRATION - difficult - studying	(109) 1	3	1	2	1	1	1	1	1		1	■		1	1		
3. SLEEP - DEEP - daytime	(16) 1		1												2	1	
4. GENERALS - FOOD and DRINKS - cold drink,...	(276) 1	2	3	2	2	1	1	2	2	2	1	1	3	3	3	2	1
5. GENERALS - FOOD and DRINKS - vegetable...	(52) 1	3	2		1	2	1	1	1	1	1		1			2	2
6. MIND - CONVERSATION - aversion to	(45) 1	1		1				1	1	1	1		2	2			

REPERTORISATION CHART XIII

13



		lach.	nux-v	puls.	bry.	sulph.	alum.	bell.	acon.	ars.	phos.	sil.	nat-c.	nat-m.	ant-c.	apis	kali-c.
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
		7	7	6	6	6	6	5	5	5	5	5	5	5	5	4	4
		11	11	11	9	9	8	10	7	7	7	7	6	6	5	10	8
4. Clipboard 4																	
1. SLEEP - DOZING	(84) 1	2	2	2	1	1	1	1	1	2	1	1	1	1	1	3	1
2. GENERALS - FOOD and DRINKS - stimulants...	(26) 1	1	2												1		
3. MIND - FEAR - vomiting; of	(2) 1	1							1								
4. SLEEP - DEEP	(278) 1	2	3	3	2	2	2	3	1	2	2	1	1	2	1	2	
5. EXTREMITIES - SHOULDERS; complaints of	(123) 1	1	1	3	3	3	2	3	3	1	2	1	2	1	1		3
6. GENERALS - COLD - applications - amel.	(26) 1		1	1	1		1	1	1	1	1	1				3	
7. GENERALS - FOOD and DRINKS - potatoes ...	(40) 1			1		1	1						1	1			
8. RECTUM - CONSTIPATION - menses - befor...	(26) 1	2	1		1	1	1					3		1	1	2	3
9. ABDOMEN - PAIN - touch - agg.	(26) 1	2	1	1	1	1		2		1	1		1				1

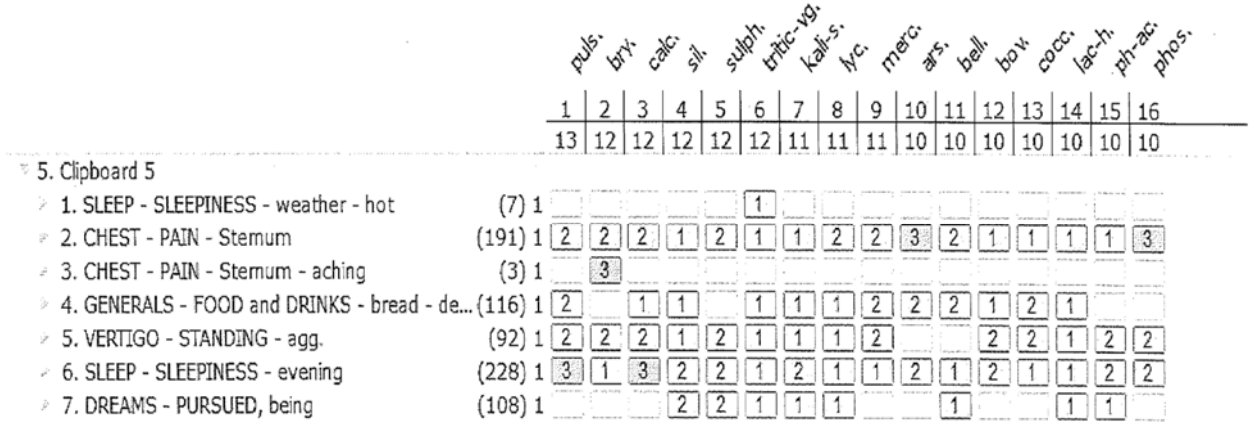
REPERTORISATION CHART XIV

14

		nux-v.	nat-m.	cham.	puls.	bell.	hell.	ign.	sep.	sulph.	lyc.	chin.	bry.	alum.	anac.	calc.	nux-m.
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
		27	25	23	23	22	22	22	22	22	21	20	19	18	17	17	17
5. Clipboard 5																	
1. HEAD - PAIN - dull pain	(296) 1	3	1	1	3	1	1	1	1	1	2	2	1	1	2	1	1
2. HEAD - PAIN - exertion - agg.	(57) 1	2	3		1	3	2		1		1		1		1	3	
3. SLEEP - DOZING	(84) 1	2	1	2	2	1	2	1		1		1	1	1	1	1	
4. EYE - PAIN - stitching pain	(196) 1	2	2	2	2	1	2	1	2	3	2	1	2	1	1	2	2
5. EYE - PAIN - wind - agg.	(4) 1				1												
6. GENERALS - FOOD and DRINKS - coffee - d...	(119) 1	1	1	1	1	1			2	1		2	2	2		1	2
7. GENERALS - FOOD and DRINKS - vegetable...	(52) 1		2			1	3	2	1	1	1				1	1	
8. GENERALS - WARM - applications - amel.	(43) 1	2		2	1		1	3	2	1		2	1	2	1		3
9. EAR - NOISE - agg.	(23) 1	1		2	1	2		1		2	1	1					
10. EYE - HEAVINESS - Lids - Upper	(22) 1	2	1	2		1	1		2	1	1		1				2
11. SLEEP - WAKING - hunger, from	(17) 1		1					2			3	1		1			
12. MIND - COMPANY - aversion to	(297) 1	3		3	2	2	2	3	3	2	2	2	2	3	3	1	1

REPERTORISATION CHART XV

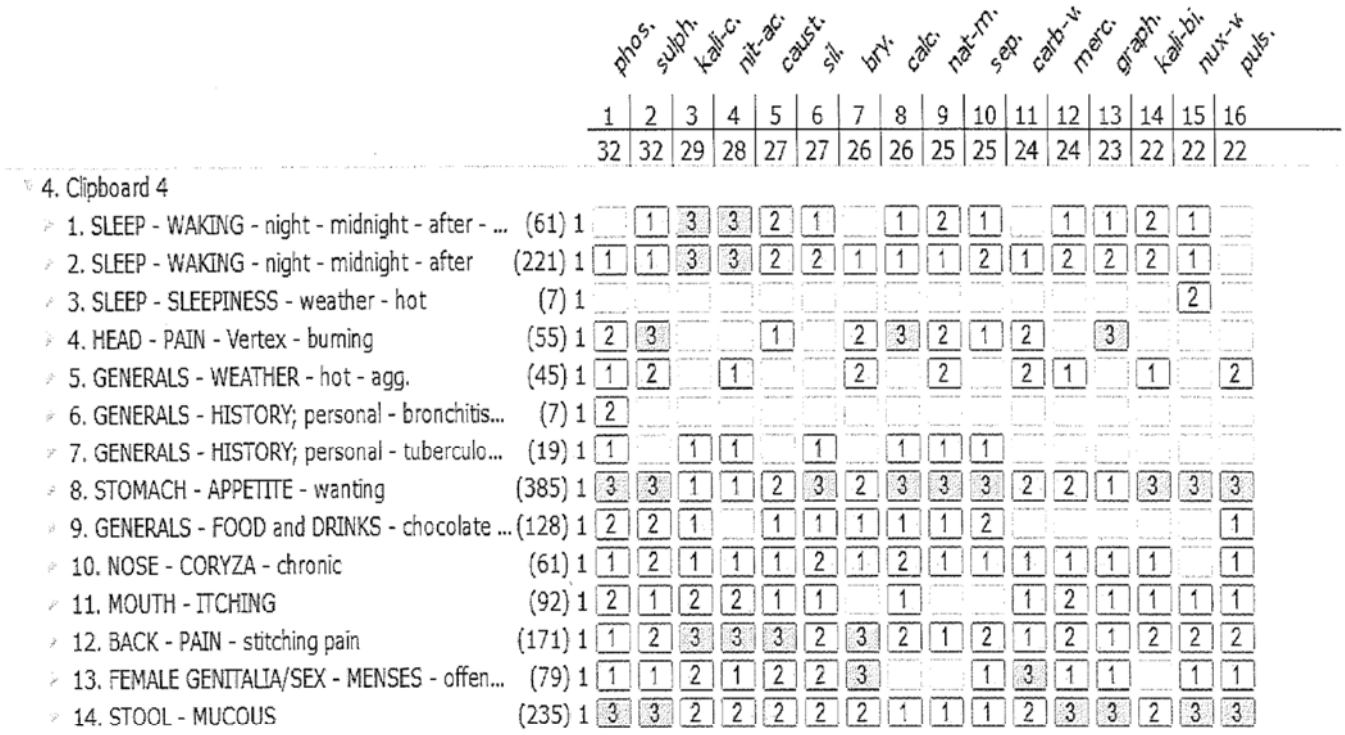
15 r



		puls.	bry.	calc.	sil.	sulph.	tritic-vg.	kali-s.	lyc.	merc.	ars.	bell.	bov.	cocc.	lac-h.	ph-ac.	phos.
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
		13	12	12	12	12	12	11	11	11	10	10	10	10	10	10	10
5. Clipboard 5																	
1. SLEEP - SLEEPINESS - weather - hot	(7) 1						1										
2. CHEST - PAIN - Sternum	(191) 1	2	2	2	1	2	1	1	2	2	3	2	1	1	1	1	3
3. CHEST - PAIN - Sternum - aching	(3) 1		3														
4. GENERALS - FOOD and DRINKS - bread - de...	(116) 1	2		1	1		1	1	1	2	2	2	1	2	1		
5. VERTIGO - STANDING - agg.	(92) 1	2	2	2	1	2	1	1	1	2			2	2	1	2	2
6. SLEEP - SLEEPINESS - evening	(228) 1	3	1	3	2	2	1	2	1	1	2	1	2	1	1	2	2
7. DREAMS - PURSUED, being	(108) 1				2	2	1	1	1			1			1	1	

REPERTORISATION CHART XVI

16 r



		phos.	sulph.	kali-c.	nit-ac.	caust.	sil.	bry.	calc.	nat-m.	sep.	carb-v.	merc.	graph.	kali-bi.	nux-v.	puls.
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
		32	32	29	28	27	27	26	26	25	25	24	24	23	22	22	22
4. Clipboard 4																	
1. SLEEP - WAKING - night - midnight - after - ...	(61) 1		1	3	3	2	1		1	2	1		1	1	2	1	
2. SLEEP - WAKING - night - midnight - after	(221) 1	1	1	3	3	2	2	1	1	1	2	1	2	2	2	1	
3. SLEEP - SLEEPINESS - weather - hot	(7) 1															2	
4. HEAD - PAIN - Vertex - burning	(55) 1	2	3			1		2	3	2	1	2		3			
5. GENERALS - WEATHER - hot - agg.	(45) 1	1	2		1			2		2		2	1		1		2
6. GENERALS - HISTORY; personal - bronchitis...	(7) 1	2															
7. GENERALS - HISTORY; personal - tuberculo...	(19) 1	1		1	1		1		1	1	1						
8. STOMACH - APPETITE - wanting	(385) 1	3	3	1	1	2	3	2	3	3	3	2	2	1	3	3	3
9. GENERALS - FOOD and DRINKS - chocolate ...	(128) 1	2	2	1		1	1	1	1	1	2						1
10. NOSE - CORYZA - chronic	(61) 1	1	2	1	1	1	2	1	2	1	1	1	1	1	1		1
11. MOUTH - ITCHING	(92) 1	2	1	2	2	1	1		1			1	2	1	1	1	1
12. BACK - PAIN - stitching pain	(171) 1	1	2	3	3	3	2	3	2	1	2	1	2	1	2	2	2
13. FEMALE GENITALIA/SEX - MENSES - offen...	(79) 1	1	1	2	1	2	2	3			1	3	1	1		1	1
14. STOOL - MUCOUS	(235) 1	3	3	2	2	2	2	2	1	1	1	2	3	3	2	3	3

REPERTORISATION CHART XVII

17.

		nux-v	phos.	lyc.	sulph.	calc.	sep.	chin.	nat-m.	bry.	graph.	nit-ac.	puls.	ars.	caust.	lach.	op.
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
		24	24	23	23	20	20	19	19	18	18	18	18	17	17	17	17
3. Clipboard 3																	
1. SLEEP - SLEEPINESS - afternoon	(233) 1	3	2	1	3	1	1	3	1	1	1	1	2	2	1	2	
2. SLEEP - SLEEPINESS - eating - after - agg.	(113) 1	3	2	2	2	3	1	2	2	1	1	1	1	1	1	1	2
3. SLEEP - UNREFRESHING	(327) 1	2	3	3	2	3	2	2	2	1	1	3	2	2	3	3	2
4. SLEEP - UNREFRESHING - morning	(38) 1	2		2	3		2		2	1	2						1
5. VERTIGO - HUNGRY, when	(8) 1																
6. THROAT - PAIN - raw; as if	(185) 1	3	2	3	2	2	1	3	2	2	2	3	2	1	3	2	1
7. MIND - FEAR - death, of	(257) 1	3	3	2	1	3	1	1	2	2	2	3	2	■	2	2	2
8. GENERALS - FOOD and DRINKS - onions - a...	(17) 1		2	1			1					1					1
9. MIND - SLOWNESS	(150) 1	1	3	1	3	2	3	2	1	3	2		3	1	1	1	1

REPERTORISATION CHART XVIII

18 18

		sulph.	nat-m.	phos.	puls.	nux-v.	lach.	bell.	lyc.	calc.	sil.	alum.	caust.	kali-bi.	acon.	kola	op.
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
		9	8	7	7	6	6	6	6	6	6	6	6	6	5	5	5
		16	11	11	11	13	11	10	10	9	9	8	8	8	7	7	7
1. Clipboard 1																	
1. EYE - HEAVINESS - Lids	(163) 1	2	2	2		2		1	2	2	1	1	3	2	1	1	1
2. SLEEP - LIGHT	(130) 1	2	1	1	1	2	3	1	2	2	2	2	1		2	2	2
3. MIND - CONCENTRATION - difficult - studying	(109) 1	1	1	1	1		1	1	1	1		1	1	1	1	2	1
4. HEAD - PAIN - pulsating pain	(203) 1	3	3	2	3	2	2	3	3	2	2	1	1	1	2	1	2
5. HEAD - PAIN - afternoon - 17 h	(15) 1	1	1		2												
6. HEAD - PAIN - lying down - amel.	(10) 1						2							1			
7. NOSE - SINUSES; complaints of	(53) 1	1	1	1	1		1	1	1	1	1			1			
8. GENERALS - FOOD and DRINKS - spices - d...	(136) 1	3	1	3	2	2			1			1	1		1	1	
9. SKIN - ERUPTIONS - pustules - itching	(26) 1	2				1	2				2			2			
10. MIND - FEAR - animals, of	(28) 1	1	1	1	1			3		1	1	2	1				1

REPERTORISATION CHART XIX

19 19

		puls.	sulph.	bell.	ars.	carb-v.	sep.	nat-m.	nux-v	sil.	phos.	ign.	colch.	lyc.	nit-ac.	lach.	fer.
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
		8	8	8	8	7	7	7	7	7	7	7	7	6	6	6	6
		18	15	13	12	17	17	16	15	15	14	12	8	14	14	13	12
2. Clipboard 2																	
1. DREAMS - FOOLISH	(3) 1												1				
2. MIND - CONCENTRATION - difficult	(433) 1	2	2	1	1	3	3	2		3	3	1	1	3	2	3	1
3. SLEEP - DEEP - afternoon	(11) 1									1		1					
4. HEAD - PAIN - pulsating pain	(203) 1	3	3	3	2	3	2	3	2	2	2	2	1	3	1	2	3
5. HEAD - PAIN - motion - agg.	(202) 1	1	1	3	1	3	2	2	2	2	2	1	1	2	3	2	2
6. HEAD - PAIN - periodical	(92) 1	2	2	1	2	2	3	3	2	3	2	2		2	3	2	2
7. SKIN - ERUPTIONS - acne	(21) 1		1	1	1	1	1		1								
8. MIND - IMPULSIVE	(59) 1	3	1		2				1		1	3				1	
9. GENERALS - FOOD and DRINKS - eggs - av...	(54) 1	2	2	1				1			1		1		2		2
10. GENERALS - FOOD and DRINKS - pork - a...	(34) 1	3		1	1	3	3	2		1			2	1			
11. STOOL - HARD	(355) 1	2	3	2	2	2	3	3	3	3	3	2	1	3	3	3	2

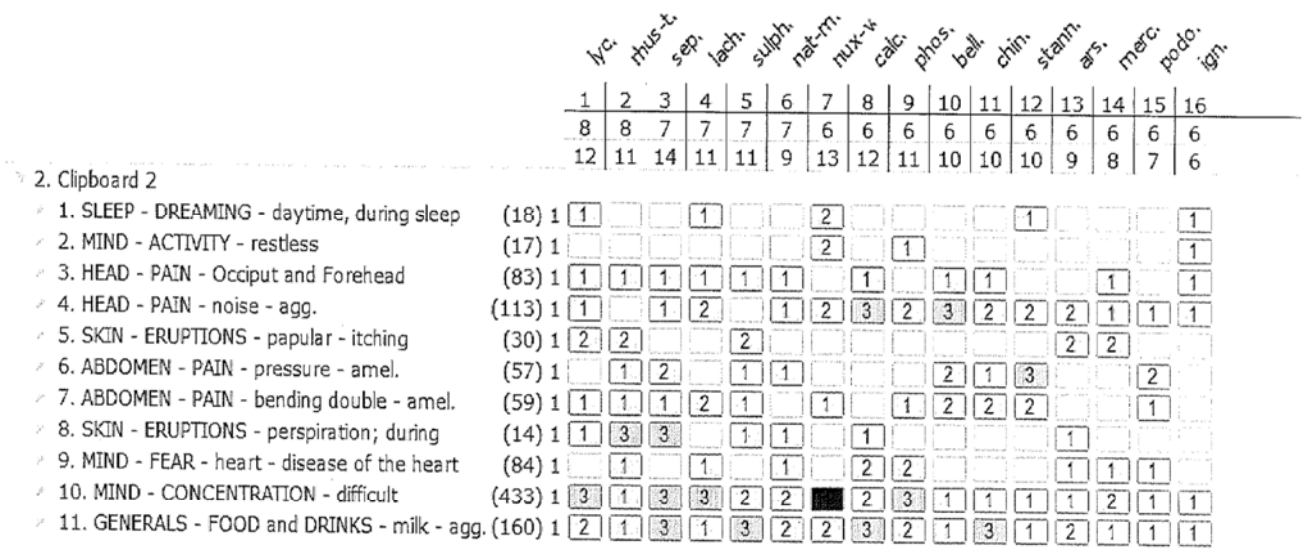
REPERTORISATION CHART XX

20

		lyc.	nat-m.	sulph.	lach.	nux-v.	nat-c.	sep.	cocc.	con.	mag-c.	nit-ac.	op.	phos.	ag-mar.	bry.	carbn-s.
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
		7	7	6	6	6	6	5	5	5	5	5	5	5	5	5	5
		11	11	11	10	9	7	9	8	7	7	6	6	6	5	5	5
1. Clipboard 1																	
1. SLEEP - SLEEPINESS - afternoon - 15 h	(17) 1		1													1	1
2. SLEEP - UNREFRESHING - morning	(38) 1	2	2	3		2		2	2	1	2		1		1	1	
3. SLEEP - HEAVY	(80) 1	1		1	1	1	1					1	1		1		1
4. STOMACH - APPETITE - diminished	(308) 1	2	1	1	2	1	1	1	1	2	1		1	1	1		1
5. GENERALS - FOOD and DRINKS - farinaceou...	(79) 1	1	2	2	1	1	1					1		1	1		
6. FEMALE GENITALIA/SEX - MENSES - irregular	(120) 1	2	1	2	2	2	2	2	2	2	1	2	1	1		1	1
7. FEMALE GENITALIA/SEX - MENSES - before ...	(41) 1	1	1		1		1	1	1	1	1	1		1		1	
8. MIND - ABSENTMINDED	(285) 1	2	3	2	3	2	1	3	2	1	2	1	2	2	1	1	1

REPERTORISATION CHART XXI

21



		lyc.	rhus-t.	sep.	lach.	sulph.	nat-m.	nux-v.	calc.	phos.	bell.	chin.	stann.	ars.	merc.	podo.	ign.
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
		8	8	7	7	7	7	6	6	6	6	6	6	6	6	6	6
		12	11	14	11	11	9	13	12	11	10	10	10	9	8	7	6
2. Clipboard 2																	
1. SLEEP - DREAMING - daytime, during sleep	(18) 1	1			1			2					1				1
2. MIND - ACTIVITY - restless	(17) 1							2		1							1
3. HEAD - PAIN - Occiput and Forehead	(83) 1	1	1	1	1	1	1		1		1	1			1		1
4. HEAD - PAIN - noise - agg.	(113) 1	1		1	2		1	2	3	2	3	2	2	2	1	1	1
5. SKIN - ERUPTIONS - papular - itching	(30) 1	2	2			2								2	2		
6. ABDOMEN - PAIN - pressure - amel.	(57) 1		1	2		1	1				2	1	3			2	
7. ABDOMEN - PAIN - bending double - amel.	(59) 1	1	1	1	2	1		1		1	2	2	2			1	
8. SKIN - ERUPTIONS - perspiration; during	(14) 1	1	3	3		1	1		1					1			
9. MIND - FEAR - heart - disease of the heart	(84) 1		1		1		1		2	2				1	1	1	
10. MIND - CONCENTRATION - difficult	(433) 1	3	1	3	3	2	2		2	3	1	1	1	1	2	1	1
11. GENERALS - FOOD and DRINKS - milk - agg.	(160) 1	2	1	3	1	3	2	2	3	2	1	3	1	2	1	1	1

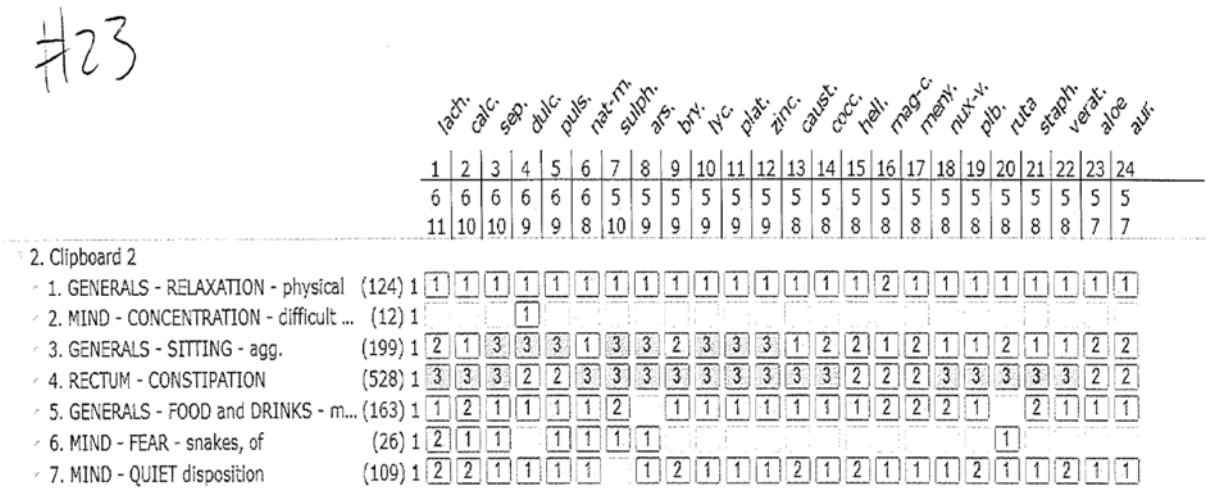
REPERTORISATION CHART XXII

22.

		phos.	lyc.	caust.	dulc.	staph.	sil.	nat-m.	kali-c.	nux-v.	sulph.	arn-c.	bell.	calc.	chin.	thus-t.	bry.	kali-bi.	kali-s.	thuj.	borx.	carc.	cina	mag-c.	mag-m.
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
		5	5	5	5	5	4	4	4	4	4	4	3	3	3	3	3	3	3	3	3	3	3	3	3
		7	6	5	5	5	8	6	5	5	5	4	5	5	5	5	4	4	4	4	3	3	3	3	3
1. Clipboard 1																									
1. GENERALS - WEARINESS - afternoon	(59) 1	1	1		1	1			1	1		1					2		1	1		1		1	1
2. SLEEP - DISTURBED - night	(13) 1																				1				
3. CHEST - SNEEZING - agg.	(20) 1	1		1			1				1		1			2	1	1			1		1		
4. GENERALS - INFLAMMATION - Sinus...	(92) 1	2	1	1	1		3	1	1	1	2	1	1	2				2	1	1		1		1	1
5. HEAD - PAIN - heat - during	(97) 1	1	1	1	1	1	3	3	1	2	1	1	3	1	3	2	1	1		2	1		1		
6. EYE - DRYNESS - sensation of	(14) 1			1		1	1								1								1		
7. GENERALS - FOOD and DRINKS - su...	(37) 1	2	2	1	1	1		1	2	1	1	1		2	1	1						1			
8. MIND - FEAR - reptiles; of	(1) 1																								
9. MIND - QUARRELLING - aversion to	(20) 1		1		1	1		1											2					1	1

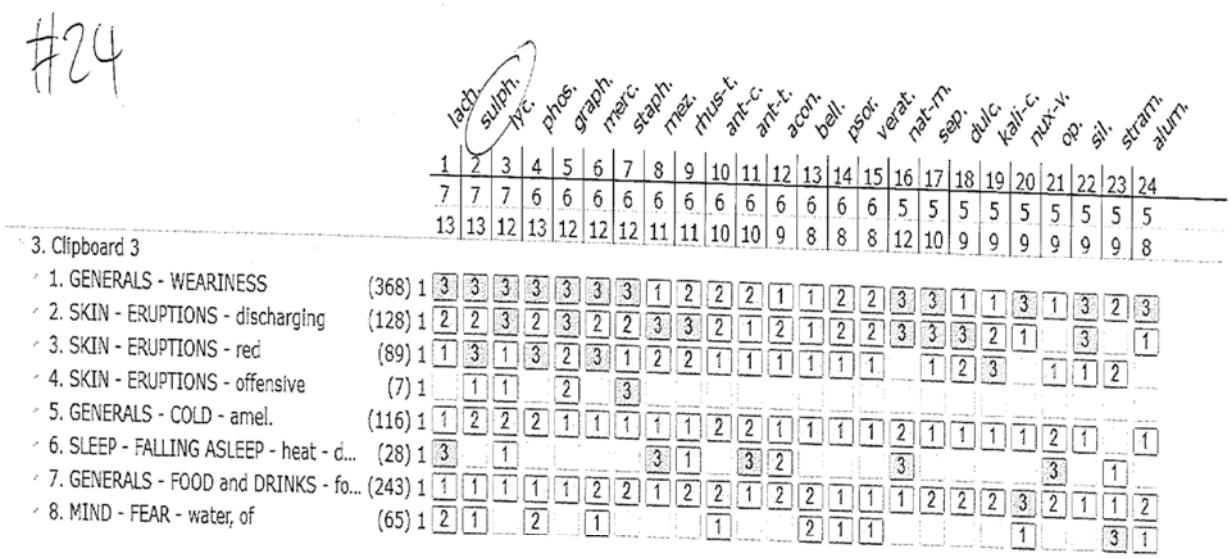
REPERTORISATION CHART XXIII

#23



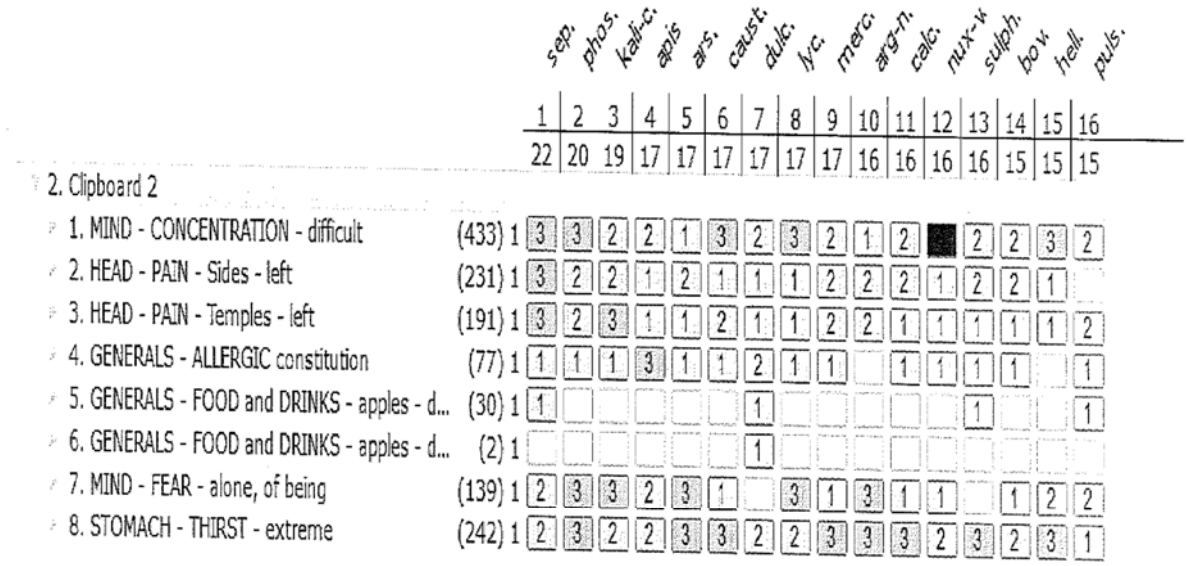
REPERTORISATION CHART XXIV

#24



REPERTORISATION CHART XXV

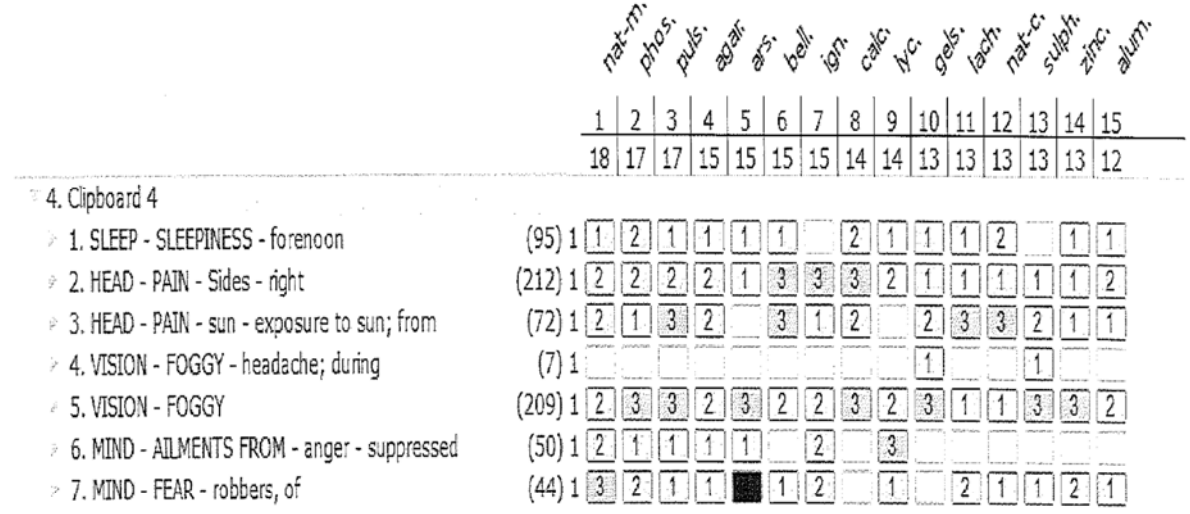
75



		sep.	phos.	kali-c.	apis	ars.	caust.	dulc.	lyc.	merc.	arg-n.	calc.	nux-v.	sulph.	bov.	hell.	puls.
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
		22	20	19	17	17	17	17	17	17	16	16	16	16	15	15	15
2. Clipboard 2																	
1. MIND - CONCENTRATION - difficult	(433) 1	3	3	2	2	1	3	2	3	2	1	2	■	2	2	3	2
2. HEAD - PAIN - Sides - left	(231) 1	3	2	2	1	2	1	1	1	2	2	2	1	2	2	1	
3. HEAD - PAIN - Temples - left	(191) 1	3	2	3	1	1	2	1	1	2	2	1	1	1	1	1	2
4. GENERALS - ALLERGIC constitution	(77) 1	1	1	1	3	1	1	2	1	1		1	1	1	1		1
5. GENERALS - FOOD and DRINKS - apples - d...	(30) 1	1						1						1			1
6. GENERALS - FOOD and DRINKS - apples - d...	(2) 1							1									
7. MIND - FEAR - alone, of being	(139) 1	2	3	3	2	3	1		3	1	3	1	1		1	2	2
8. STOMACH - THIRST - extreme	(242) 1	2	3	2	2	3	3	2	2	3	3	3	2	3	2	3	1

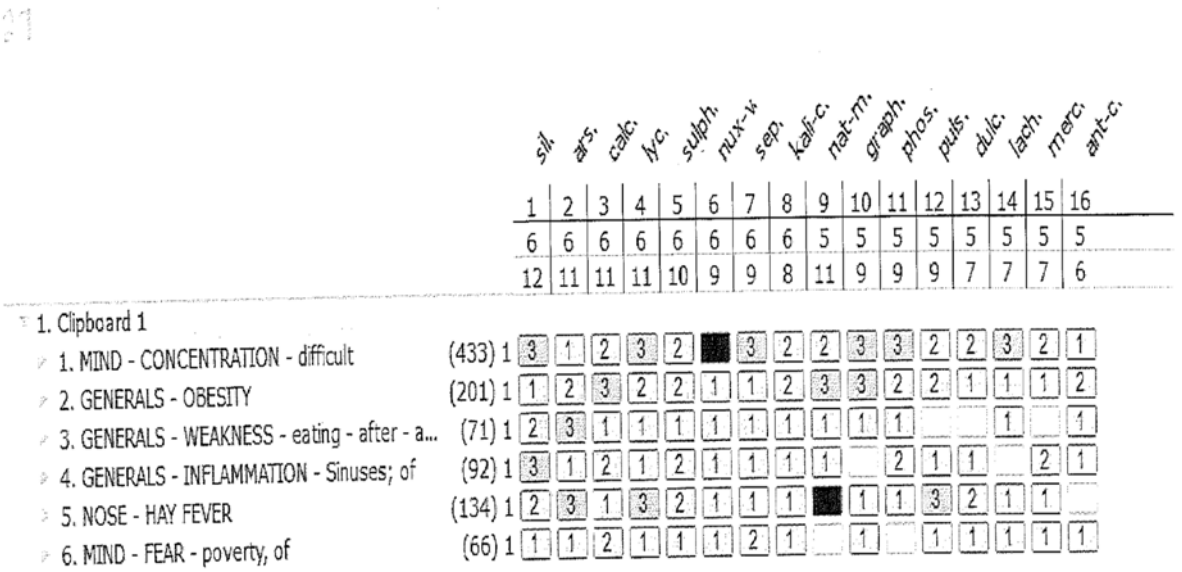
REPERTORISATION CHART XXVI

26



		nat-m.	phos.	puls.	agar.	ars.	bell.	ign.	calc.	lyc.	gels.	lach.	nat-c.	sulph.	zinc.	alum.
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
		18	17	17	15	15	15	15	14	14	13	13	13	13	13	12
4. Clipboard 4																
1. SLEEP - SLEEPINESS - forenoon	(95) 1	1	2	1	1	1	1		2	1	1	1	2		1	1
2. HEAD - PAIN - Sides - right	(212) 1	2	2	2	2	1	3	3	3	2	1	1	1	1	1	2
3. HEAD - PAIN - sun - exposure to sun; from	(72) 1	2	1	3	2		3	1	2		2	3	3	2	1	1
4. VISION - FOGGY - headache; during	(7) 1										1			1		
5. VISION - FOGGY	(209) 1	2	3	3	2	3	2	2	3	2	3	1	1	3	3	2
6. MIND - AILMENTS FROM - anger - suppressed	(50) 1	2	1	1	1	1		2		3						
7. MIND - FEAR - robbers, of	(44) 1	3	2	1	1		1	2		1		2	1	1	2	1

REPERTORISATION CHART XXVII



		sil.	ars.	calc.	lyc.	sulph.	nux-v.	sep.	kali-c.	nat-m.	graph.	phos.	puls.	dulc.	lach.	merc.	ant-c.
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
		6	6	6	6	6	6	6	6	5	5	5	5	5	5	5	5
		12	11	11	11	10	9	9	8	11	9	9	9	7	7	7	6
1. Clipboard 1																	
1. MIND - CONCENTRATION - difficult	(433) 1	3	1	2	3	2	■	3	2	2	3	3	2	2	3	2	1
2. GENERALS - OBESITY	(201) 1	1	2	3	2	2	1	1	2	3	3	2	2	1	1	1	2
3. GENERALS - WEAKNESS - eating - after - a...	(71) 1	2	3	1	1	1	1	1	1	1	1	1			1		1
4. GENERALS - INFLAMMATION - Sinuses; of	(92) 1	3	1	2	1	2	1	1	1	1		2	1	1		2	1
5. NOSE - HAY FEVER	(134) 1	2	3	1	3	2	1	1	1	■	1	1	3	2	1	1	
6. MIND - FEAR - poverty, of	(66) 1	1	1	2	1	1	1	2	1		1		1	1	1	1	1

REPERTORISATION CHART XXVIII

38

		phos.	sulph.	lyc.	med.	carc.	adam.	falco-pe.	iach.	sil.	calc.	iod.	sep.	staph.	hell.	cann-i.	caust.
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
		5	5	4	4	3	3	3	3	3	3	3	3	3	2	2	2
		12	9	6	5	5	4	4	4	4	3	3	3	3	4	3	3
2. Clipboard 2																	
1. HEAD - PAIN - fasting agg.	(37) 1	3	3	3			2		1	2	1	1	1				1
2. MIND - SYMPATHETIC	(99) 1	3	1	1	1	3	1	2	1		1	1	1	1	1	1	2
3. MIND - ART - ability for	(16) 1	1	1		1	1		1		1				1			
4. MIND - ACTIVITY - desires activity - creative ...	(60) 1	2	2	1	2	1	1	1	2	1	1	1		1		2	
5. MIND - ANSWERING - slowly	(42) 1	3	2	1	1								1		3		

REPERTORISATION CHART XXIX

29

		nat-m.	staph.	lyc.	sep.	ign.	tritic-vg.	aur-m-n.	sulph.	lach.	aur-s.	aur.	caust.	con.	nux-v	puls.	arg-n.
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
		22	20	19	18	16	16	15	15	14	13	13	12	12	12	12	11
3. Clipboard 3																	
1. GENERALS - FOOD and DRINKS - coffee - d...	(119) 1	1	1		2		1	2	1	1	1	2		2	1	1	1
2. MIND - COMPANY - aversion to	(297) 1		3	2	3	3	2	2	2	2	2	2	1	2	3	2	2
3. MIND - DWELLS - past disagreeable occurre...	(84) 1		1	3	2	3	1	2	2		1		1	2		1	1
4. MIND - FEAR - narrow place, in	(110) 1	1	1	2	1	2	2	2	1	1			1		1	2	3
5. MIND - TIMIDITY - public; about appearing i...	(13) 1		1	2			1			1							
6. GENERALS - HISTORY; personal - cystitis; o...	(18) 1		3	1	1					1					1	1	
7. MIND - AILMENTS FROM - love; disappointed	(57) 1		3		1			2	1	2	2	3	2	2	1		
8. MIND - AILMENTS FROM - rejected; from b...	(13) 1	2		3	1		3		2		2	2	2				

REPERTORISATION CHART XXX

30

		cimic.	cact.	lyc.	cann-s.	ran-s.	spig.	sulph.	verat.	calc.	cann-i.	carb-an.	cocc.	cupr.	mag-c.	nat-c.	nit-ac.
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
		14	10	10	8	8	8	8	8	7	7	7	7	7	7	7	7
5. Clipboard 5																	
1. SLEEP - FALLING ASLEEP - easy	(13) 1			1											1	1	
2. HEAD - PAIN - Vertex	(376) 1	3	3	2	2	3	2	3	3	1	2	3	1	2	2	2	2
3. HEAD - VERTEX; complaints of	(125) 1	1	2	2	1	3	2	1	3	2		2	1	1	1	1	3
4. HEAD - OPENING - sensation as if opened a...	(3) 1	1					1										
5. HEAD - OPENING - sensation as if opened a...	(5) 1	2															
6. HEAD - PAIN - opening and shutting; as if	(19) 1	2	2	1	2			1		1	3		2	1			

REPERTORISATION CHART XXXI

31

		nat-m.	sil.	alum.	calc.	nux-v.	sulph.	lach.	lyc.	bell.	bry.	kali-c.	merc.	ars.	puls.	aur.	chin.
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
		33	32	30	29	27	27	25	25	23	23	23	23	22	22	21	21
1. Clipboard 1																	
1. HEAD - PAIN - sleep - after - agg.	(124) 1	3	2	1	2	2	2	3	2	2	2	2	1	1	1	2	1
2. HEAD - PAIN - extending to - Cervical region	(59) 1	1	2			2		2	1	1	2	1	1				1
3. EYE - PAIN - sand; as from	(156) 1	3	2	1	3		3	1	2	1	1	1	1	3	2	2	3
4. EYE - PHOTOPHOBIA	(270) 1	3	2	2	3	3	3	2	3	3	2	2	3	3	2	2	3
5. STOMACH - APPETITE - wanting	(385) 1	3	3	2	3	3	3	1	3	1	2	1	2	3	3	1	3
6. RECTUM - DIARRHEA - morning	(189) 1	1	1	1	2	2	3	1	2	1	3	2	2	2	2	1	1
7. STOOL - YELLOW	(249) 1	1		1	2	1	1	2	3	1	2	2	3	2	1	1	2
8. GENERALS - FOOD and DRINKS - indigestibl...	(26) 1	1	3	2	2	1	1	3	1	1	1				1	2	
9. GENERALS - FOOD and DRINKS - chalk - de...	(19) 1	2	1	3	1	2	1								2		
10. GENERALS - FOOD and DRINKS - lime, slat...	(20) 1	1	2	2	2	2	1										
11. DREAMS - SNAKES	(66) 1		1	1				1		1		1					
12. DREAMS - ROBBERS	(66) 1	3	2	3						1		2	2	1		2	