

**The efficacy of homoeopathic simillimum in the treatment of  
attention-deficit/hyperactivity disorder (AD/HD) in  
schoolgoing children aged 6-11 years.**

**by**

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Degree in Technology: Homoeopathy in the Faculty of Health Sciences at the Durban  
University of Technology.

I, Megan Jones do declare that this dissertation is representative of my own work, both  
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## **DEDICATION**

This dissertation is dedicated to my Cape Town Family and my Durban Family.

Thank you for the support over all these years.

## **ACKNOWLEDGEMENTS**

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**Staff at Homoeopathic Day Clinic**

**The parents/guardians and children who participated in the trial.**

## **ABSTRACT**

### **INTRODUCTION**

The aim of this study was to evaluate the efficacy of homoeopathic simillimum in the treatment of attention-deficit/hyperactivity disorder (AD/HD) in schoolgoing children aged 6-11 years. AD/HD affects approximately 3-5% of children worldwide. It is thus a highly prevalent childhood disorder characterised by hyperactivity, impulsivity and restlessness. There are 3 subtypes of the condition, namely combined type, predominantly inattentive type and predominantly hyperactive-impulsive type (DSM-IV-TR, 2000 pg 90).

### **OBJECTIVE**

The objective of the study was to determine the efficacy of homoeopathic simillimum in the treatment of this disorder, and thus promote homoeopathy as a safe alternative to conventional AD/HD treatments.

### **METHODOLOGY**

The study was conducted as a double-blind placebo-controlled study. The sample group consisted of 30 participants. There was an experimental group of 16, which was compared to a placebo control group of 14. Participants were recruited from the greater Durban area. They had to satisfy clear inclusion and exclusion criteria. Participants and parents/guardians were required to attend 3 consultations with the researcher at The Homoeopathic Day Clinic over a 2-month period. The ADHD Rating Scale-IV Home and School Versions (Appendices B and C) had to be completed by the participant's parent/guardian and teacher respectively. One was filled in at the initial consultation to serve as a baseline reading, and thereafter, every month. Remedies were dispensed at the first 2 consultations and these remedies were decided upon after thorough case-

taking, use of Radar 9.0 Homoeopathic Software and discussion with 1 of 2 selected clinicians. Those on placebo were given free treatment at the end of the study.

## **RESULTS**

Statistical analysis was conducted on the ADHD Rating Scales-IV Home and School Versions (Appendices B and C), completed by the parent/guardian and teacher respectively. Improvement was based on a decrease in the rating scale score.

On analysis, the results (Table 4.8, 4.9 and 4.10) showed no statistically significant effect of treatment (i.e. no difference between treatment and placebo group), but across the whole trial and within each group (particularly the treatment group) subjects had significant reductions in symptoms (i.e. the reductions in symptoms were large enough that there was less than 5% chance that they were random fluctuations/effects). This was seen in both the treatment and placebo groups, as indicated by Table 4.11, 4.12 and 4.13, but more significant reductions were seen in the treatment group, indicated by Table 4.14. As discussed in Chapter 5, this by no means rules out the efficacy of homoeopathic simillimum for the treatment of AD/HD.

## **CONCLUSIONS**

A large number of parents, teachers and doctors are seeking a safe, effective way to treat this highly prevalent disorder (Soreff & Chang, 2008) and, although the study did not satisfy the hypothesis that homoeopathic simillimum is an effective treatment for AD/HD in schoolgoing children, it did aid in creating awareness of the use of homoeopathy as a treatment option for this condition and highlighted the need for more extensive research to be undertaken for this treatment option. It is the researcher's opinion that larger, longer duration

studies, employing quantitative analysis, as well as qualitative analysis would yield more significant results.

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## LIST OF DEFINITIONS AND ABBREVIATIONS:

- ❑ **Allopathy:** A term for orthodox or standard medicine. Based on the roots *allo-* meaning *other*, and *pathos* meaning *suffering* (Gray, 2000 pg 159).
- ❑ **Attention deficit-hyperactivity disorder (AD/HD):** A disorder of childhood and adolescence manifested at home, in school, and in social situations by developmentally inappropriate degrees of inattention and impulsivity (Dirckx, 2001).
- ❑ **Axis I Disorder:** A clinical disorders or other condition that may be a focus of clinical attention, according to the DSM-IV multiaxial system (DSM-IV-TR, 2000).
- ❑ **Bipolar Disorder:** An affective disorder characterised by the occurrence of alternating periods of euphoria (mania) and depression (Dirckx, 2001).
- ❑ **Centesimal (CH):** The most commonly used scale in homoeopathy, based on serial dilutions of 1/100 (Vithoulkas, 2004 pg 164).
- ❑ **Computed tomography (CT) scan:** An image of anatomical information from a cross-sectional plane of the body, each image generated by a computer synthesis of x-ray transmission data (Dirckx, 2001).
- ❑ **Conduct Disorder:** A disorder characterised by a repetitive and persistent pattern of behaviour in which the basic rights of others or major age-appropriate societal norms or rules are violated (DSM-IV-TR, 2000 pg 93).

- ❑ **Convenience sampling:** A method that removes bias from the selection of participants, whereby any participant who fulfils the study criteria and is able to be compliant during the study period, is accepted into the sample group (Dirckx, 2001).
  
- ❑ **Double blind:** A study conducted with neither the researcher nor participants knowing which participants are in the control group (i.e. placebo group). This is to prevent bias in recording results (Dirckx, 2001).
  
- ❑ **Electroencephalogram (EEG):** A record obtained from observing the electric potentials of the brain, derived from electrodes attached to the scalp (Dirckx, 2001).
  
- ❑ **Essential Fatty Acids (EFA):** These are linoleic acids, required by the body for the formation of various eicosanoids, such as prostaglandins, thromboxanes and leukotrienes (Beers, 2006).
  
- ❑ **Feingold Diet:** A dietary approach to treating AD/HD that includes the elimination of food colourings, additives, preservatives, flavourings, and salicylates (Reichenberg-Ullman & Ullman, 2000 pg 286).
  
- ❑ **Homoeopathy:** A system of therapy developed by Samuel Hahnemann based on the “law of infinitesimal doses” and *similia similibus curantur* (likes are cured by likes) (Dirckx, 2001).
  
- ❑ **Infinitesimal dose:** The idea that much smaller doses of the drug are needed to bring about a reaction in the diseased body, as homoeopathy is based on the paradigm of healing that the patient brings about the cure

after remedies stimulate the patient's curative powers (De Schepper, 2006 pg 39).

- ❑ **Law of Similars:** The fundamental tenet of homoeopathy that states that a substance which causes a set of symptoms in a healthy person acts as a curative medicine when given to sick people who have its similar symptoms (Cummings & Ullman, 1997).
- ❑ **Materia medica:** A book that includes individual homoeopathic remedies and their indications (Reichenberg-Ullman & Ullman, 2000 pg 286).
- ❑ **Millesimal (M):** A potency scale made by 1 in 100 dilutions carried out 1000 times (Kayne, 2006).
- ❑ **Oppositional Defiant Disorder (ODD):** A disorder characterised by a recurrent pattern of negativistic, defiant, disobedient, and hostile behaviour toward authority figures that persists for at least 6 months (DSM-IV-TR, 2000 pg 100).
- ❑ **Placebo:** An inert compound identical in appearance to material being tested in experimental research, which may or may not be known to the physician and/or patient, administered to distinguish between drug action and suggestive effect of the material under study (Dirckx, 2001).
- ❑ **Plussed potency:** Remedies given in water when frequent repetition is required (Vithoulkas, 2004 pg 263). It is based on the ability of potentized water to transmit its potency to unmedicated water (Gray, 2000 pg 160).

- ❑ **Polychrest:** A remedy suitable for a number of illnesses, disorders or symptoms (Guide to Homeopathy, 1999).
  
- ❑ **Potency:** The strength of a homoeopathic medicine, as determined by the number of serial dilutions and successions (Reichenberg-Ullman & Ullman, 2000 pg 287).
  
- ❑ **Potentization:** The process of serial dilution and succussion of a solution, thereby increasing its effectiveness as a homoeopathic remedy when prescribed according to the Similia Principle (Gray, 2000 pg 160).
  
- ❑ **Prostaglandins:** These are extremely active hormone-like substances that are derived from EFAs. They are vital to healthy functioning (Holford, 2004 pg 71).
  
- ❑ **Qualitative results:** These are results that represent the nature of the improvement (Dirckx, 2001).
  
- ❑ **Quantitative results:** These are results that represent the amount of improvement (Dirckx, 2001).
  
- ❑ **Quinquagenimillesimal (LM):** A potency made by diluting the remedy in a ratio of 1 to 50 000 at each step, succussed 100 times at each dilution (De Schepper, 2006 pg 88).
  
- ❑ **Randomisation:** Assignment of the subjects of experimental research to groups by chance (Dirckx, 2001).



- **Reliable Change Index (RCI):** The RCI is calculated by dividing the difference of the pre- and post-treatment scores by the standard error of difference (given by age and gender). A value of 1.96 or above signified a clinically significant ( $p=0.05$ ) reduction in symptoms, which is not attributed to observer error (DuPaul, Power, Anastopoulos & Reid, 1998).
- **Repertory:** A book or software programme of remedy drug pictures classified with reference to symptoms, developed to organise the vast amount of information of materia medica (Kayne, 2006 pg 192).
- **Rubric:** A symptom that is listed in the repertory (Cummings & Ullman, 1997).
- **Similia:** A Greek word meaning “similar”; used in reference to the law of similars (Cummings & Ullman, 1997).
- **Simillimum:** The homoeopathic medicine prescribed according to the Law of Similars that most clearly matches the symptoms of the patient and that produces the greatest benefit (Reichenberg-Ullman & Ullman, 2000 pg 288).
- **Succussion:** The systematic and repeated shaking of a homoeopathic medicine after each serial dilution (Reichenberg-Ullman & Ullman, 2000 pg 288).
- **Tic Disorder:** A symptom picture characterized by twitches, jerks, and other convulsive or uncontrollable behaviours (Reichenberg-Ullman & Ullman, 2000 pg 288).

- ❑ **Totality of Symptoms:** A comprehensive picture of the whole person: physical, mental, and emotional (Reichenberg-Ullman & Ullman, 2000 pg 288), achieved after thorough case-taking.
  
- ❑ **Tourette's Syndrome:** A specific type of tic disorder that includes jerking, throat clearing, swearing, and other uncontrollable nervous system behaviours (Reichenberg-Ullman & Ullman, 2000 pg 288).
  
- ❑ **Vital Force:** This is the energy force within the body (De Schepper, 2006 pg 12).

## **CHAPTER 1: INTRODUCTION**

Attention-deficit/hyperactivity disorder (AD/HD) is a syndrome of inattention, hyperactivity, and impulsivity. The DSM-IV states that approximately 3-7% of children worldwide currently have AD/HD (DSM-IV-TR, 2000 pg 90), and thus it appears to be a highly prevalent disorder. However, many experts feel that AD/HD is over-diagnosed, largely because criteria are applied inaccurately (Beers, 2006 pg 2483).

The 3 types of AD/HD are predominantly inattentive, predominantly hyperactive-impulsive, and combined type. Diagnosis is made by clinical criteria, according to the Diagnostic and Statistical Manual of Diagnosis and Therapy (DSM-IV) (Beers, 2006 pg 2483).

Despite extensive research, a clear, single causative mechanism has yet to be established. Potential causes include genetic, biochemical, head trauma, prenatal alcohol, tobacco and cocaine exposure, physiological, and behavioural factors (Beers, 2006 pg 2483). Research to establish clear causative factors is ongoing.

Multimodal treatment is advised and should consist of medication, behavioural therapy, and educational accommodations (DuPaul & Weyandt, 2006). Allopathic medicines used include psychostimulants, atomoxetine, antidepressants and antihypertensives, and these all have a substantial risk of side-effects. Common adverse effects associated with psychostimulants, the most commonly prescribed class of drug for this condition, include loss of appetite with subsequent loss of weight, headaches, nausea, abdominal pain, sleeplessness and depression (Picton, 2005). Health care providers, parents, and teachers are seeking effective therapies and methods that do not involve these medicines (Soreff & Chang, 2008).

## **PROBLEM STATEMENT**

The aim of this study was to evaluate the efficacy of homoeopathic simillimum in the treatment of AD/HD in school going children, aged 6-11 years, by means of the ADHD Rating Scale-IV. (Appendices B and C) Both the Home and School Versions were applied to determine results across 2 settings.

## **OBJECTIVES**

The first objective proposed to determine the effectiveness of homoeopathic simillimum in the management of AD/HD symptoms.

The second objective proposed to determine the effectiveness of placebo in the management of AD/HD symptoms.

The third objective proposed to integrate the results of the placebo and treatment groups in order to determine if there is a difference in the efficacies of homoeopathic simillimum and placebo in the management of this condition.

The fourth objective proposed to determine the presence and significance of correlations between demographic descriptors, remedy breakdown and potency breakdown with responses to treatment.

This study therefore proposed to investigate the efficacy of homoeopathic simillimum in the treatment of AD/HD, as an effective and safe alternative to existing treatment options.

## **HYPOTHESES**

The first hypothesis was that homoeopathic simillimum would have no beneficial effects in the management of AD/HD symptoms according to the ADHD Rating Scale-IV (Appendices B and C).

The second hypothesis was that there would be no difference in effects between the treatment and placebo groups in the treatment of AD/HD symptoms according to the ADHD Rating Scale-IV (Appendices B and C).

## **CHAPTER 2: LITERATURE REVIEW**

### **2.1 HISTORY**

In about 1902, in its early history as a distinctly recognisable phenomenon, attention-deficit/hyperactivity disorder (AD/HD) was seen as a problem in the way that children learnt to wilfully inhibit their behaviour and adhere to rules of social conduct. Over the next few decades, scientists moved away from trying to define the disorder to concentrating more on its possible causes (Barkley, 2005 pg 41). In the fifties it was believed that minimum brain injury was the cause of the condition and it was called 'minimum brain damage', which was subsequently replaced by 'minimum brain dysfunction' (Picton, 2005 pg 3), after no underlying brain damage was found in most of the children (Barkley, 2005 pg 41). In the seventies and early eighties the term 'hyperactive' was commonly used, with the emphasis placed on the aspect of over-activity (Picton, 2005 pg 3). The disorder then became known as 'hyperactive child syndrome'. Research then shifted onto the nature of attention, its different types and which types were involved in the disorder. At this point the disorder was renamed 'attention deficit disorder' (ADD). In 1980, due to the fact that some children had attention problems but were not hyperactive, the American Psychiatric Association created two subtypes of ADD; ADD with, and without hyperactivity. In 1987 the terminology was amending to 'attention deficit hyperactivity disorder'. It is currently known as attention-deficit/hyperactivity disorder. The Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) uses the term AD/HD to refer to all of the subtypes (Barkley, 2005 pg 41, 162).

### **2.2 CLINICAL PICTURE**

AD/HD is an Axis I childhood disorder, characterised by inattention, restlessness, impulsivity, and hyperactivity. Axis I disorders are clinical disorders and other conditions that may be a focus of clinical attention (DSM-IV-TR, 2000 pg 27, 85). AD/HD characteristics cause disruption and create socio-environmental problems for the child (Kronenberger, 2000). They are

not developmentally appropriate for the child's age (DuPaul & Weyandt, 2006). Parents are likely to first notice the characteristics when a child is 3-4 years old, or in some cases, even younger (Barkley, 2005 pg 112).

According to DSM-IV criteria, the child must have at least 6 of the below-mentioned symptoms of inattention or hyperactivity-impulsivity. They must be present for at least 6 months and be more severe than is normally observed in individuals at a comparative level of development. These symptoms must be persistent and noted before the age of 7. They should cause clinically significant impairment (e.g. in social, academic, or occupational functioning) and must be present in at least two settings (e.g. home and school). Symptoms must not occur exclusively during the course of a Pervasive Developmental Disorder, Schizophrenia, or other Psychotic Disorder or be better accounted for by another mental disorder (e.g. Mood disorder, Anxiety disorder, Dissociative disorder, or a Personality disorder) (DSM-IV-TR, 2000 pg 85, 93) (Appendix A).

Symptoms of inattention:

- fails to give close attention to details or makes careless mistakes in schoolwork, or other activities
- has difficulty sustaining attention in tasks or play activities
- does not seem to listen when spoken to directly
- does not follow through on instructions and fails to finish schoolwork, chores, or duties
- has difficulty organizing tasks and activities
- avoids, dislikes, or is reluctant to engage in tasks that require sustained mental effort (such as schoolwork or homework)
- loses things necessary for tasks or activities (e.g. toys, school assignments, pencils, books, or tools)
- is easily distracted by extraneous stimuli

- is forgetful in daily activities

Symptoms of hyperactivity-impulsivity:

- fidgets with hands or feet, or squirms in seat
- leaves seat in classroom or in other situations in which remaining seated is expected
- runs about or climbs excessively in situations in which it is inappropriate
- has difficulty playing or engaging in leisure activities quietly
- is “on the go” or acts as if “driven by a motor”
- talks excessively
- blurts out answers before questions have been completed
- has difficulty awaiting turn
- interrupts or intrudes on others

Many individuals present with characteristics of both inattention and hyperactivity-impulsivity, however there are individuals in whom one or the other pattern is predominant. The appropriate subtype (for a current diagnosis) should be diagnosed based on the predominant symptom pattern for the past 6 months (DSM-VR-TR, 2000 pg 87). DSM-IV has created 3 subcategories, namely:

**1. Attention-deficit/hyperactivity disorder, Combined Type.**

**2. Attention-deficit/hyperactivity disorder, Predominantly Inattentive Type**



### **3. Attention-deficit/hyperactivity disorder, Predominantly Hyperactive-Impulsive Type**

In the case where standard criteria for AD/HD is not met, or where symptoms are not severe enough, they are diagnosed with an atypical form of AD/HD called attention-deficit/hyperactivity disorder not otherwise specified, or AD/HD-NOS (Sonna, 2005 pg 3).

#### **2.2.1 COMBINED TYPE**

This subtype is used if 6 or more symptoms of inattention and 6 (or more) symptoms of hyperactivity-impulsivity have persisted for at least 6 months (DSM-IV-TR, 2000 pg 87). The combined type represents the majority of AD/HD children (Davison & Neale, 2001).

#### **2.2.2 PREDOMINANTLY INATTENTIVE TYPE**

This subtype is used if 6 (or more) symptoms of inattention (but fewer than 6 symptoms of hyperactivity-impulsivity) have persisted for at least 6 months (DSM-IV-TR, 2000 pg 87). An individual with this subtype is disorganized, distracted, and forgetful (Sonna, 2005 pg v). They are commonly more passive, fearful or apprehensive about things. They may be lethargic, sluggish or slow-moving, and inattentive to what is happening around them, demonstrating considerably less aggression, impulsivity and over-activity than children with the more impulsive subtype. There appears to be a significant problem with sustained attention, attention span and persistence of effort as well as memory, perceptual-motor speed, and the speed at which the brain processes incoming information (Barkley, 2005 pg 43, 48, 162, 163). Problems regarding self-esteem and academic performance are common (Sonna, 2005 pg v), resulting in difficulties in school and in completing homework (Wilens, 2008).

### **2.2.3 PREDOMINANTLY HYPERACTIVE-IMPULSIVE TYPE**

This subtype should be used if 6 (or more) symptoms of hyperactivity-impulsivity (but fewer than 6 symptoms of inattention) have persisted for at least 6 months (DSM-IV-TR, 2000 pg 87). An individual with the predominantly hyperactive-impulsive subtype is exceptionally active, restless and impulsive (Sonuga-Barke, 2005 pg v), coming across as more uninhibited and demanding. The hyperactive component is often demonstrated as fidgeting, pacing, excessive talking or other movement (Barkley, 2005 pg 6, 48, 51). They often have difficulty learning in a traditional academic environment, resulting in defiant behaviour (Sonuga-Barke, 2005 pg v) yet some perform acceptably academically and show their difficulties at home or in situations with less guidance and structure (Wilens, 2008). It is found that different symptoms may dominate at different times of life yet most individuals will display characteristics of hyperactivity throughout their life (Picton, 2005 pg 4).

As with most conditions, there are degrees of the disorder within the population; some people have mild or even borderline AD/HD, whilst others have moderate or severe AD/HD. As far as intelligence, children with AD/HD represent the entire spectrum of intellectual development (Barkley, 2005 pg 109, 121).

## **2.3 DIAGNOSIS**

Diagnosing psychiatric disorders in children is far from an exact science and the absence of objective evaluation methods and relying on the observations and opinions of parents and teachers introduces uncertainty into the diagnostic process (Barkley, 2005 pg 165). It is thus a highly subjective process and symptoms of AD/HD vary across settings, making it hard to diagnose (NIMH, 2008 pg 2).

Because specific aetiology for AD/HD is unknown, there are no laboratory tests, neurological assessments, or attentional assessments that have been

established as diagnostic in the clinical assessment of AD/HD (DSM-IV-TR, 2000 pg 88). Thus the diagnosis relies on behavioural symptoms and ruling out other disorders (ADHD In-Depth Report, 2008 pg 4). When a child's hyperactivity, distractibility, poor concentration, or impulsivity impact performance in school, social relationships, or behaviour at home, AD/HD may be suspected (NIMH, 2008 pg 2).

In order to diagnose AD/HD, substantial information about the child and family must be obtained. This information must be sifted through to establish symptoms of AD/HD and rule out other disorders or problems (Barkley, 2005 pg 152). Ideally the assessment gathers information from multiple informants who have observed the child in diverse situations. This multidimensional approach to behavioural assessment is crucial as AD/HD children often behave differently in different situations. Both cognitive and behavioural components of AD/HD must be assessed in order to understand the pattern of symptoms for the individual child. A comprehensive AD/HD assessment leads to conclusions as to the presence, severity, type, and characteristics of the disorder in the child (Kronenberger, 2000 pg 49). The final diagnosis of AD/HD is made by careful clinical history, applying the DSM-IV criteria (Wilens, 2008).

Medical assessment focuses on identifying potentially treatable conditions that may contribute or worsen symptoms and signs (Beers, 2006 pg 2484). The clinical history involves investigating the child's genetic background, pregnancy and birth events, developmental and medical history, nutritional status, and gross sensory-motor development. Thyroid problems, lead poisoning, anaemia and other illnesses that could produce symptoms that mimic AD/HD must be ruled out. A brief neurological exam to screen for relatively gross neurological problems may be conducted. Weight, height and head circumference must be measured and compared to normal standards. Hearing and vision must be screened. If a seizure disorder is suspected,

additional tests such as an electroencephalogram (EEG) or computed tomography (CT) scan may be done (Barkley, 2005 pg 161).

Often with careful testing many of the children diagnosed with AD/HD fail to meet the criteria. Factors contributing to misdiagnosis include children who are young for their grade and thus socially and intellectually immature. Social and economic problems such as single parent households also add to misdiagnosis (ADHD In-Depth Report, 2008 pg 2). Adequate diagnosis requires not only medical investigation but special psychological and educational assessment too (Methylphenidate, 2008). Psychologists are trained not only to evaluate psychological problems in children, but also to conduct psychological, learning and neuropsychological tests that can help pinpoint the type of disorder a child has (Barkley, 2005 pg 146).

In this study, participants had to be diagnosed by a child psychologist or paediatrician to ensure legitimate diagnoses.

## **2.4 DIFFERENTIAL DIAGNOSIS AND RELATED CONDITIONS**

Two-thirds of children diagnosed with AD/HD have at least one other psychiatric diagnosis (e.g. depression or anxiety disorder) (Sonna, 2005 pg 55, 57). These related conditions make it harder to diagnose and treat AD/HD (Nordqvist, 2007).

Associated features vary depending on the child's age and developmental stage. They include low frustration tolerance, temper outbursts, bossiness, stubbornness, excessive and frequent insistence that requests be met, mood lability, demoralization, rejection by peers, and poor self-esteem. It may be difficult to distinguish characteristics of AD/HD from age-appropriate behaviours in young, active children (e.g. running around or being noisy). The increased motor activity that may occur in the hyperactive subtypes of AD/HD must also be distinguished from repetitive motor behaviour characterising

Stereotypical Movement Disorder. In Stereotypical Movement Disorder, the motor behaviour is mostly focused and fixed, whereas the fidgeting and restlessness seen in AD/HD is more generalised. Characteristics of inattention are common among children with a low intelligence quotient (IQ) who are placed in academic environments that are intellectually inappropriate for their ability. In children with mental retardation, an additional diagnosis of AD/HD should be made only if the symptoms of inattention or hyperactivity are excessive for the child's mental age. Children of high intelligence may have problems with inattention that could be misdiagnosed as AD/HD when placed in an academically under-stimulating environment. These characteristics must be distinguished from those of children with AD/HD (DSM-IV-TR, 2000 pg 88, 91).

The difficulties faced by AD/HD children may also be exacerbated by one or more of the following conditions: (Picton, 2005 pg 125)

- ❑ Visual problems
- ❑ Learning difficulties related to visual perception
- ❑ Speech, language and listening difficulties
- ❑ Difficulties putting sounds together when learning to read
- ❑ Emotional problems
- ❑ Learning and remedial difficulties
- ❑ Behavioural problems
- ❑ Fine and gross co-ordination
- ❑ Inappropriate sensory modulation
- ❑ Delayed developmental milestones
- ❑ Tourette's Syndrome

As many as a third to half of children with AD/HD – mostly boys - have oppositional defiant disorder (ODD) and 20-40% may eventually develop

conduct disorder (CD) (NIMH, 2008 pg 10). Oppositional defiant behaviour is a disorder characterised by a recurrent pattern of negativistic, defiant, disobedient, and hostile behaviour toward authority figures. Conduct disorder is a disorder characterised by a repetitive and persistent pattern of behaviour in which the basic rights of others, or major age-appropriate societal norms or rules are violated (DSM-IV-TR, 2000 pg 93, 100). Between 7-10 years of age, at least 30-50% of children with AD/HD are likely to develop signs of CD and antisocial behaviour (Barkley, 2005 pg 115). Some children with AD/HD have co-occurring anxiety or depression (NIMH, 2008 pg 10). They may also exhibit symptoms of anxiety and depression that do not qualify for a formal psychiatric diagnosis (Barkley, 2005 pg 127, 128.) If these disorders are recognized and treated, the child will be able to handle the problems that accompany AD/HD more productively. There are no accurate statistics as to how many children with AD/HD have co-existing bipolar disorder. Differentiating between the two in childhood can be challenging (NIMH, 2008 pg 10). Other associated disorders may include mood disorders and communication disorders (DSM-IV-TR, 2000 pg 88).

Children with AD/HD are more likely to have learning disabilities. They may have specific problems in speech development, expressive language and fluency (Barkley, 2005 pg 122, 123). Academic deficits and school-related problems tend to be more pronounced in the types marked by inattention, whereas peer rejection and accidental injury are more common in the types marked by hyperactivity and impulsivity (DSM-IV-TR, 2000 pg 88).

AD/HD appears in approximately 50% of clinic-referred children with Tourette's Syndrome, a tic disorder, yet most individuals with AD/HD do not have the accompanying syndrome (DSM-IV-TR, 2000 pg 88). It has been suggested that the same gene could be responsible for Tourette's Syndrome and AD/HD (Picton, 2005 pg 132) yet it seems more likely that AD/HD is simply a co-morbidity of Tourette's Syndrome.

There are not really any specific physical features associated with AD/HD, although minor physical anomalies (e.g. hypertelorism (abnormal distance between two paired organs), highly arched palate, low-set ears) may occur more frequently than in the general population (DSM-IV-TR, 2000 pg 89). Children with AD/HD seem more likely to have visual problems and seem to have more problems with general health, which is as yet a misunderstood association (Barkley, 2005 pg 124, 126). There may also be a higher rate of accidental physical injury (DSM-IV-TR, 2000 pg 89).

## **2.5 EPIDEMIOLOGY**

Epidemiological studies indicate a high prevalence of AD/HD throughout the world (Wilens, 2008). There is no definite consensus on the incidence rate of hyperactivity and figures differ according to the source of information (Picton, 2005 pg 3). It is a current argument as to whether it is over-diagnosed or under-diagnosed (ADHD In-Depth Report, 2008 pg 1). It is estimated that 2-5% of children have AD/HD, or approximately 2 million in the United States (NIMH, 2006). The DSM-IV states that approximately 3-7% of children worldwide currently have AD/HD (DSM-IV-TR, 2000 pg 90). Studies done in a number of countries over the last 10-15 years have revealed that AD/HD exists in every country and in every ethnic group studied. Some available statistics include New Zealand, 2-7%; Germany 4%; India, 5-29%; China, 6-9%; Japan, 7-8% and Brazil, 5-6% (Barkley, 2005 pg 111).

It is unknown whether these figures reflect an increase in the incidence of AD/HD, or simply a better recognition of it. It may also be an indication of a culture that places excessive emphasis on normalcy and academic achievement at the expense of over-diagnoses (ADHD In-Depth Report, 2008 pg 1).

The disorder is up to three times more prevalent amongst boys than girls (Barkley, 2005 pg 111), although the predominantly inattentive type occurs with equal frequency in both sexes (Beers, 2006 pg 2483). Boys are more

likely to be referred to clinics because they have a higher likelihood of aggression and antisocial behaviour (Davison & Neale, 2001). Thus more girls with AD/HD may go unrecognised and untreated (Barkley, 2005 pg 112).

Not much is known about AD/HD on the African continent. A study, published in the South African Journal of Psychology (2004:34) on cross-cultural similarities in AD/HD-like behaviour amongst South African primary school children (Meyer, Eilertsen, Sundet, Tshifularo, & Sagvolden, 2004), was conducted using data from 6094 primary school children from six language groups in the Limpopo Province. The study aimed to shed greater light on social effects within South African cultures, and between South African, United States (US) and European cultures, in the context of AD/HD. In the study, the teachers completed a shortened version of the Disruptive Behaviour Disorders (DBDs) rating scale (available at [http://www.ccf.buffalo.edu/pdf/DBD\\_rating\\_scale.pdf](http://www.ccf.buffalo.edu/pdf/DBD_rating_scale.pdf)), a DSM-IV criteria-based scale, and this data was analysed. The study proved that AD/HD is not specific to US and European cultures and that the prevalence of AD/HD subtypes was comparable to US and European rates. Surprisingly small cultural differences in the prevalence of AD/HD-like behaviour were also shown to exist between South African cultures (Meyer *et al*, 2004 pg 122-138).

## **2.6 AETIOLOGY**

Although AD/HD is one of the most extensively studied of all the childhood psychological disorders, it remains misunderstood and controversial in the minds of the general public as well as the medical profession. The difficulties in producing direct scientific proof that any specific factor or factors cause a problem with human behaviour must be kept in mind. Behavioural scientists are often left with information that is highly suggestive of a cause but not proven with absolute certainty. Intense interest in understanding and treating AD/HD has instigated voluminous research. It is commonly accepted that AD/HD has multiple causes and, since the mid-1980s knowledge of these causes and how they influence the brain and behaviour has increased



significantly (Barkley, 2005 pg xiv, 29, 78). A vast number of different theories on AD/HD have been suggested, but so far there has not been one that fully accounts for all aspects (and all occurrences) of the condition (Picton, 2005 pg 9).

Possible causes include genetics, brain developmental delays, brain injury or damage, neurotransmitter problems, environmental factors, complications of pregnancy and delivery, nutritional influences and heavy metal intoxication.

### **2.6.1 GENETICS**

Most substantiated causes of AD/HD appear to fall within the realm of neurobiological and genetic causes (NIMH, 2008 pg 7). Evidence is quickly accumulating that suggests that AD/HD is a disorder in brain development or brain functioning that originates in genetics (Barkley, 2005 pg 26). Adoption studies (e.g. Van den Oord, Boomsma & Verhulst, 1994) and numerous large-scale twin studies (e.g. Levy, Hay, McStephen, Wood & Waldman, 1997) indicate that this proposed genetic predisposition may play a role in AD/HD (Davison & Neale, 2001). The specific factors inherited in AD/HD probably include a tendency toward problems in the development of the frontal cortex of the brain as well as the caudate nucleus (Barkley, 2005 pg 90), however it's precise neural and pathophysiological substrate remains unknown (Wilens, 2008).

There is a 40% chance that at least one parent of a child with AD/HD also has the disorder and approximately 15-20% of mothers and 20-30% of fathers of children with the condition may have it at the same time as their children. Having a sibling with AD/HD increases the likelihood to 25-35% that another child in the family will have AD/HD. The risk is about 13-17% for girls and 27-30% for boys, regardless of the sex of the sibling. These figures point to genetic causative factors. Biological relatives of children with AD/HD also have more psychological problems (particularly depression, alcoholism, conduct problems, antisocial behaviour, and hyperactivity) than those of

children without AD/HD (Barkley, 2005 pg 89, 102, 132, 138, 139), further suggestive of a genetic link.

Researchers continue to study the genetic contribution to AD/HD and are currently working at identifying the specific genes that cause a susceptibility to AD/HD (NIMH, 2008 pg 8).

### **2.6.2 BRAIN DEVELOPMENT**

Differences in brain functioning, structure and development are indicated. It has been found that the frontal lobes of children with AD/HD are under-responsive to stimulation and that cerebral blood flow is reduced. Parts of the brain, including the frontal lobes, caudate nucleus and globus pallidus, have also been found to be smaller than normal. There is also poor performance in frontal lobe functioning in neurophysiological tests. Neurological studies indicate that in AD/HD children the brain has developed differently but is not damaged (Davison & Neale, 2001).

An Imaging study by Shaw, Rapoport & Evans, published in 2007 by the National Institute of Mental Health (NIMH) has revealed that the brain matures in a normal pattern in children with AD/HD but is delayed an average of three years in some regions, compared to children without the disorder. They discovered a normal yet delayed pattern of cortex maturation, which could explain why many children eventually outgrow their AD/HD. The greatest maturational delay was seen in the circuitry of the frontal and temporal areas. This area integrates information from the sensory areas with higher-order functions. The motor cortex was found to develop faster in these children, possibly due to their hyperactive component. Although the AD/HD group initially had a thinner cortex, after being re-scanned approximately 5.7 years later, changes between the AD/HD and the control group were much greater in those children whose AD/HD symptoms had not improved and, in the children who had much improvement the scans resembled that of healthy

peers (NIMH, 2006). The findings of the study support theories that AD/HD results from a delay in cortex maturation (NIMH, 2007).

Cross-cultural consistencies in AD/HD behaviour may also be seen to support these neurobiological and genetic explanations of AD/HD (Meyer *et al.*, 2004).

### **2.6.3 BRAIN INJURY OR DAMAGE**

Children who have suffered accidents resulting in brain injury may show signs of behaviour similar to that of AD/HD, but only a small percentage of children with AD/HD have been found to have suffered a traumatic brain injury (NIMH, 2008 pg 8). Children suffering significant trauma to the frontal part of their brain are more likely to develop symptoms of AD/HD as a consequence. Any process that disrupts the normal development or functioning of the frontal part of the brain, and its connections to the striatum (caudate nucleus and putamen) is likely to result in AD/HD (Barkley, 2005 pg 27).

### **2.6.4 NEUROTRANSMITTERS**

The neurotransmitters responsible for attention and motor behaviour are the catecholamines. These are namely dopamine, norepinephrine and epinephrine. The catecholamine hypothesis that AD/HD is caused by a deficiency in these neurotransmitters stems from the fact that drugs (e.g. methylphenidate and dextroamphetamine) used to treat AD/HD increase the amount of catecholamines in the brain. There is however no direct evidence that these children suffer a catecholamine deficit (Kronenberger, 2000 pg 48).

### **2.6.5 ENVIRONMENTAL FACTORS**

There are psychological theories for the development of AD/HD (Wolfe, 2005). Although chaotic family life and parental psychiatric problems are associated with, and may well cause, serious defiant and aggressive behaviour, they are not causative of AD/HD (Barkley, 2005 pg 100). There is

a scarcity of compelling evidence at this time that AD/HD can arise purely from social factors or child-rearing methods. Environmental factors may influence the severity of the disorder, and the degree of impairment and suffering the child may experience, but they do not appear to give rise to the condition by themselves (NIMH, 2008 pg 7). Many of these children's problems may be exacerbated by inadequate teachers, unsuitable educational settings, or problems with their parents (Wolfe, 2005).

#### **2.6.6 COMPLICATIONS OF PREGNANCY AND DELIVERY**

Mothers who experienced complications of pregnancy or delivery are more likely to have children with AD/HD than those without complications. Complications may cause AD/HD by interfering with the normal brain development of the foetus (Barkley, 2005 pg 102).

Smoking cigarettes during pregnancy has been shown to cause significant abnormalities in the development of the caudate nucleus and the frontal regions of the brain. The combination of nicotine exposure both during and after pregnancy creates the greatest likelihood of significant behavioural problems (Barkley, 2005 pg 88). Nicotine stimulates dopamine release in the brain, resulting in hyperactivity (Davison & Neale, 2001). Alcohol consumption during pregnancy has also been shown to have a similar effect on the development of the caudate nucleus and the frontal regions of the brain. Foetal Alcohol Syndrome, a specific pattern of foetal malformation, found among offspring of mothers who are chronic alcoholics, leads to a heightened risk of AD/HD (Barkley, 2005 pg 27, 88).

A very basic requirement that may be overlooked is optimum nutrition during pregnancy. The brain is the most vulnerable organ in the body and sub optimal nutrition during foetal development has a profound effect on the brain, learning and behaviour (Holford, 2004 pg 358).

Low birth weight (<1000g) is sometimes associated with AD/HD (Beers, 2006), yet most children with low birth weight do not develop AD/HD, and most children with AD/HD do not have a history of low birth weight (DSM-IV-TR, 2000 pg 88). Babies born prematurely and with low birth weights may have a higher likelihood of developing AD/HD in later childhood – sometimes 5 to 7 times that of the general population. This may be due to the fact that these babies have a high risk of suffering small brain haemorrhages during delivery (Barkley, 2005 pg 103). It seems that the combination of prematurity and low birth weight is the greater risk.

The following complications before or during birth increase the risk of AD/HD: (Barkley, 2005 pg 103)

- ❑ Number of cigarettes smoked by the mother per day
- ❑ Seizures in the mother
- ❑ Number of times hospitalised during the pregnancy
- ❑ Breathing problems in the child during or after delivery
- ❑ Amniotic fluid stained by meconium (a sign of foetal hypoxic distress)
- ❑ Weight and health of the placenta when inspected after delivery

Children less healthy during their infancy or preschool years and slow to develop in motor coordination are at a higher risk for early and persistent AD/HD symptoms later in childhood (Barkley, 2005 pg 103).

## **2.6.7 NUTRITIONAL INFLUENCES**

Nutritional deficiencies in AD/HD children could severely increase the problems they already face. Identifying and correcting existing deficiencies may not only clear up some of the problems but may help the child cope more effectively with those that remain (Picton, 2005 pg 53). Some of the most important nutrients for brain development are absent in the average modern diet (Holford, 2004 pg 358).

Symptoms of essential fatty acid (EFA) deficiency are common in many children with AD/HD. These include excessive thirst, dry skin, eczema and asthma. An aspect to consider is the fact that males have a higher EFA requirement than females and 4 out of 5 AD/HD sufferers are boys. This suggests a possible correlation that requires more research. It is theorised that these children are deficient in EFAs due to inadequate dietary intake, higher requirements, poor absorption or poor conversion of them into prostaglandins. Prostaglandins are essential for brain communication. Many of the foods claimed to cause symptoms of AD/HD, such as dairy and wheat, inhibit EFA conversion into prostaglandins. Various enzymes are involved in the conversion and they require various vitamins and minerals to function. These include vitamin B3, B6 and C, biotin, zinc and magnesium, all commonly found deficiencies in AD/HD children (Holford, 2004 pg 358).

More than 60% of AD/HD children are short of zinc. This is often a result of the refining process applied to certain foods, namely white sugar, white flour, and white rice. Consuming primarily refined grains increases the risk of nutritional deficiencies developing. Nutrients such as zinc and the B vitamins are found in the whole grain, but not in the refined product. B Vitamins are important for regulation of the nervous system and metabolism of proteins, fats and carbohydrates. Hair analysis reveals that hyperactive children also often have very low levels of manganese (Picton, 2005 pg 47, 48, 55, 57).

Faulty digestion and absorption are also factors to be considered. Common problematic foods include wheat, high in gluten and dairy products containing casein. These proteins are difficult to digest and may result in an allergy. The poor digestion of these proteins is a result of zinc-deficiency, and they enter the bloodstream due to Vitamin A and EFA deficiencies. The peptides making up these proteins are able to mimic endorphins in the brain. They are referred to as exorphins and have a damaging opioid-like effect on the brain, leading to symptoms seen in children with behaviour problems (Holford, 2004 pg 360).

It has been found that iron deficiency causes abnormal dopaminergic neurotransmission and thus this deficiency may contribute to the physiopathology of AD/HD. A study conducted by Konofal, Lecendreux, Arnulf & Mouren (2004) found that mean serum ferritin levels were twice as low in children with AD/HD when compared to age- and sex-matched children without AD/HD. It was also found that the low levels correlated with more severe AD/HD general symptoms, according to Conners' Parent Rating Scale (available at <http://www.pearsonassessments.com/tests/crs-r.htm>), a 48-item scale that includes hyperactivity, cognitive, and oppositional subscales. The reason for the low serum ferritin levels is unclear. Supplementing with iron could thus improve central dopaminergic activity in these children, decreasing the need for stimulants (Konofal *et al*, 2004).

Allergies or food intolerance can decrease the effect of any therapies being used to treat AD/HD. Common signs and symptoms of food and chemical intolerance include fatigue, headaches, migraine, hyperactivity, disturbed sleep, restlessness, poor attention span, learning difficulties and aggression. Foods that may affect hyperactive children include chocolate, wheat, tomato, eggs, cows' milk, cheese and sugar (Picton, 2005 pg 75, 77).

Food additives and refined sugar have been blamed for AD/HD in the past but have been found to only account for a very small percentage of the cases (Davison & Neale, 2001).

#### **2.6.8 HEAVY METAL INTOXICATION**

Evidence has been surfacing over a number of decades that industrial chemicals can cause neurodevelopmental damage and that sub-clinical stages of these disorders might be more common than previously realised (Grandjean & Landrigan, 2006 pg 1). Heavy metal intoxication results from the absorption of heavy metals. It can lead to autism, hyperactivity and psychosis. The main culprits are aluminium, lead and cadmium. Aluminium foil, pots and pans should be avoided (Picton, 2005 pg 58, 59). Lead, a neurotoxic

chemical, produces lifelong changes in behaviour, attention span, impulsivity, aggressiveness, motor coordination, memory, and language skills (Grandjean & Landrigan, 2006 pg 8). It is a potential cause of inattention, hyperactivity or even fully-fledged AD/HD in some cases (Barkley, 2005 pg 89). Other effects include mental retardation, temper tantrums, and emotional and behavioural problems. Increased levels of lead in the body cause a reduction in the levels of zinc, iron and copper. Levels of cadmium are increased by cigarette smoke, tobacco and refined wheat flour. Too much cadmium in the body lowers zinc levels (Picton, 2005 pg 58, 59).

## **2.7 MANAGEMENT/TREATMENT**

One of the most complex aspects in the treatment of AD/HD is that it must evolve as a child grows up. A treatment that was successful at age 6 may not work at age 16 (Barkley, 2005 pg 112).

Most children require help from a variety of disciplines, and the period of time that they attend the different therapists depends on the individual needs of the child and the nature of the therapy. A team approach is usually needed with both the parents and the professionals playing a role in the child reaching his/her best potential (Picton, 2005 pg 26). The Multimodal Treatment Study of Children with AD/HD was a 14-month randomised clinical trial of treatment strategies for the condition. It was conducted on 579 elementary school boys and girls with AD/HD. The results of the study indicated that long-term combination treatments and medication-management alone were superior to intensive behavioural treatment and routine community treatment. The advantage of combined treatment was that children could be treated with lower doses of medicine, compared with the medication-only group (NIMH, 2008 pg 11). Multimodal treatment should consist of medication, behavioural therapy, and educational accommodations (DuPaul & Weyandt, 2006). This is not quite a realistic goal for standardised AD/HD treatment in the South African context due to financial constraints.



The management of AD/HD traditionally includes consideration of 2 major areas: nonpharmacological and pharmacotherapy (Wilens, 2008).

### **2.7.1 PSYCHOLOGICAL TREATMENT**

Behaviour therapy, emotional counselling, and practical support help AD/HD children handle everyday problems (NIMH, 2008 pg 14), whilst environmental changes are implemented to decrease limitations caused by AD/HD (Davison & Neale, 2001). Behavioural therapy teaches people how to develop effective ways to work on immediate issues, helping to change their thinking and coping strategies, thus leading to changes in behaviour. In social skills the therapist discusses, teaches and models appropriate behaviours that are important in developing and maintaining social relationships (NIMH, 2008 pg 15).

### **2.7.2 REMEDIAL SCHOOLS**

In some cases remedial schools may be of benefit. These schools have the facilities to accommodate specific learning problems, and after a few years the child is able to return to the mainstream school system better able to cope with academic demands. These schools offer small classes with individualised attention. The teachers are qualified to handle learning problems. Many remedial institutes offer a multidisciplinary approach for assessing children and provide excellent service. Speech therapists, occupational therapists and remedial therapists are usually part of the support team (Picton, 2005 pg 27).

### **2.7.3 MEDICATION**

Currently, more than 2.5 million children in the United States are being prescribed AD/HD medications (Mozes, 2008). These medications are probably the most widely publicised and debated treatment for AD/HD (Barkley, 2005 pg 319).

A possible social cause of the rise in prescription AD/HD medications may be the lowering of public education budgets, resulting in larger classes in which the teachers are far less tolerant of hyperactive behaviour (Frei & Thurneysen, 2001).

Medications are not intended for use in cases where symptoms are secondary to environmental factors and/or primary psychiatric disorders, including psychosis (Methylphenidate, 2008). There is a need for detailed, accurate, and comprehensive assessment by trained and experienced practitioners before starting AD/HD treatment (Coghill, 2004). The diagnosis of AD/HD should not constitute automatic drug treatment (Barkley, 2005 pg 335).

At present much less is known about treating the inattentive subtype than the hyperactive-impulsive subtype. The hyperactive-impulsive subtype demonstrate a much greater therapeutic response to medication, with a 55-65% lower response demonstrated by the inattentive subtype (Barkley, 2005 pg 163, 164, 335). Psychotropic medication, whilst often being effective in improving attention and decreasing disruptive behaviour, is not always associated with marked enhancement of academic functioning (DuPaul & Weyandt, 2006), personal relationships or quality of life (Landgraf, Rich & Rappaport, 2002 pg 386).

Medications include psychostimulants, atomoxetine, antidepressants and antihypertensives.

#### **2.7.3.1 PSYCHOSTIMULANTS**

Conventional treatment for AD/HD consists of psychostimulants (Davison & Neale, 2001). The more commonly used compounds in this class include methylphenidate (Ritalin®, Metadate® and Concerta®), amphetamine (Dexedrine®, Dextrostat®, and Adderall®), and magnesium pemoline (Cylert®) (Wilens, 2008; Soreff & Chang, 2008).

Stimulants are sympathomimetic drugs, which increase intrasynaptic catecholamines (mainly dopamine) via inhibition of the presynaptic reuptake mechanism and the release of catecholamines (Wilens, 2008). The precise mode of action is not completely understood but they are presumed to activate the brain stem arousal system and cortex, producing a stimulatory effect (Methylphenidate, 2008). They deal directly with the under-active part of the brain that is responsible for inhibiting behaviour and maintaining effort or attention to things (Barkley, 2005 pg 323, 327).

The stimulants improve the child's attention, impulse control, fine motor coordination and reaction time (Barkley, 2005 pg 328), enhancing and normalising a child's natural abilities to focus, reflect and achieve academically, socially and behaviourally (Green, 1997). They have shown to be effective in improving behaviour, academic work and social adjustment in 50-90% of children with AD/HD, however 30-45% of children will have significant behavioural improvements but not normalise (Barkley, 2005 pg 319, 323). About one-third of these children do not respond, or cannot tolerate this class of drug (Wilens, 2008). The greatest benefit of this therapy seems to be that it increases the effectiveness of psychological and educational treatments. Thus, it is usually recommended that medication be used as apart of a combination of treatments, not as the sole form of therapy (Barkley, 2005 pg 328).

These drugs are available in short-acting and long-acting dosage forms. The short-acting forms are taken a number of times a day, including during school hours. A rebound effect may occur as the drug effect wears off, intensifying AD/HD symptoms. Thus the long-acting dosage forms have become more popular (ADHD In-Depth Report, 2008 pg 8). Stimulants are usually given orally for AD/HD treatment (Barkley, 2005 pg 329), with the exception of Daytrana®, the first skin patch drug for AD/HD. The patch is applied to the hip daily and delivers a 9-hour dose of methylphenidate (ADHD In-Depth Report, 2008 pg 8).

Common adverse effects associated with stimulants include loss of appetite with subsequent loss of weight, headaches, nausea, abdominal pain, sleeplessness and depression (Picton, 2005). Antidepressants and other medications can help control accompanying depression or anxiety (NIMH, 2008 pg 13). Although a causal relationship has not been established, suppression of growth (i.e. weight gain and/or height) has been associated with the long-term use of stimulants in children. Methylphenidate may lower the convulsion threshold in patients with prior history of seizures (Methylphenidate, 2008). AD/HD stimulants increase a child's heart rate and blood pressure. Children with underlying heart disease who take stimulants appear to face an increased risk for sudden cardiac arrest. The American Heart Association recommends cardiac screening before prescribing stimulant treatment for all children diagnosed with AD/HD. They recommend taking a detailed patient and family medical history, a full physical exam, including blood pressure and heart beat monitoring; an electrocardiogram (ECG); and a paediatric cardiologist consultation prior to treatment if evidence of heart disease is uncovered. Children should continue to have blood pressure check-ups once every 1 to 3 months, as well as routine check-ups every 6 to 12 months (Mozes, 2008). Some children experience "behavioural rebound" as the stimulant wears off at the end of the school day. Other potential side effects include an increase in hyperactive behaviour (Kronenberger, 2000) and approximately 15% of children placed on stimulants may develop simple tics or nervous mannerisms (Barkley, 2005 pg 332). Methylphenidate may rarely cause hepatitis (Wilens, 2008).

Methylphenidate should not be used in children under 6 years of age, since safety and efficacy in this age group have not been established. Available clinical data indicates that treatment with stimulants during childhood and/or adolescence does not seem to result in increased predisposition for addiction (Methylphenidate, 2008) however, there are no long-term studies on the potential long-term negative effects that might be caused by persistent use of these medications (Barkley, 2005 pg 331).

### **2.7.3.2 NON-STIMULANTS: ATOMOXETINE**

Strattera, a non-stimulant drug, works by increasing the levels of the neurotransmitter norepinephrine (NIMH, 2008 pg 13; ADHD In-Depth Report, 2008 pg 8), with 70% of children manifesting significant improvement in their AD/HD symptoms (NIMH, 2008 pg 13). There is, however, a warning that Strattera increased suicidal tendencies in children and adolescents with AD/HD (Aschenbrenner, 2006), thus patients on this treatment should be closely monitored.

### **2.7.3.3 ANTIDEPRESSANTS**

Although not as effective as the psychostimulants, these drugs can be of some benefit in the treatment of AD/HD in cases where there has been an inadequate response to stimulant medication, unacceptable side effects from medication, or in cases where a comorbid condition such as depression, anxiety disorder, is present. They are not as effective as the stimulants in improving the symptoms of AD/HD and they are often combined with one of the stimulants to achieve optimal results (Barkley, 2005 pg 339, 340).

#### **i. TRICYCLIC ANTIDEPRESSANTS**

Tricyclic antidepressants act by blocking the re-uptake of neurotransmitters, including norepinephrine. They are effective in controlling abnormal behaviours and improving cognitive impairments associated with AD/HD, but less so than the majority of stimulants (Wilens, 2008).

Possible side-effects include increase risk of seizures or convulsions, dry mouth, constipation, weight gain, blurred vision, nearsightedness, slowed heart rate, nervous tics, rash and photophobia. Children may develop a tolerance to the tricyclic antidepressants, so usually they cannot take these medicines for more than a year or two (Barkley, 2005 pg 341, 342).

## **ii. BUPROPION**

Bupropion (Wellbutrin®, Zyban®) is an antidepressant with indirect dopamine and noradrenergic effects, often used as an initial agent for complex AD/HD patients with substance abuse or unstable mood disorder. Possible side effects include increased activity, irritability, insomnia, and rarely seizures (Wilens, 2008).

### **2.7.3.4 ANTIHYPERTENSIVES**

The antihypertensives clonidine (Catapres®) and guanfacine (Tenex®) are used in the treatment of the hyperactive-impulsive symptoms of AD/HD. These alpha-2 agonists stimulate the neurotransmitter norepinephrine (ADHD In-Depth Report, 2008 pg 9), reduce motor hyperactivity and impulsiveness, increase a child's cooperativeness and increase the child's tolerance for frustration. They are best suited for very oppositional or defiant cases, in cases with associated conduct disorder or in the treatment of children with AD/HD who have adverse effects with, or get no beneficial effects from the stimulants (Barkley, 2005 pg 343, 344). They are also used to treat the associated tics, aggression, and sleep disturbances of AD/HD, particularly in younger children (Wilens, 2008).

Sedation is more commonly seen with clonidine, but both agents may cause depression and rebound hypertension (Wilens, 2008). Other potential side effects include a drop in blood pressure, tiredness, headaches, dizziness, nausea, stomach-aches, vomiting, dry mouth, depression, erratic heart rate, disturbed sleep, increased appetite, with increase or decrease in weight, and increased anxiety, Raynaud's syndrome or water retention (Barkley, 2005 pg 344).

### **2.7.4 DIET**

Various diets have been suggested to treat AD/HD. Studies are quite conflicting as to their efficacy. A number of well-conducted studies have

shown poor efficacy in dietary restriction of sugar and food additives on behaviour, although there are improvements in a small percentage of cases. In other cases, behavioural improvements are shown with allergen-restricted diets (ADHD In-Depth Report, 2008).

The Feingold Diet was originally devised for patients suffering from allergies. It was soon noticed that the behaviour of many hyperactive children improved dramatically when put on the same diet. The diet avoids salicylates, synthetic flavours and colourants, selected preservatives and some natural foods. Chemical antioxidants are avoided and fried foods kept to a minimum. Unrefined and unprocessed foods are preferable and vitamin, mineral and essential fatty acid supplementation is important. Most hyperactive children cannot tolerate artificial salicylates and these should be avoided. Many hyperactive children can tolerate natural salicylates but one must check for sensitivity to them. Some hyperactive children may be affected by the close relatives of salicylates found in some non-edible products such as certain synthetic fibres, insecticides, detergents, some antiseptics, ventalin, and methyl salicylate which is found in many cough medicines (Picton, 2005 pg 39, 43, 44).

It is essential that a child with AD/HD obtains optimal nutrition and supplementation may be necessary (Lesperance, 2006). From the time that the child is no longer breast-fed and is relying on solid food for nutrients, supplementation of a child's diet is recommended. Most companies have a single multivitamin and mineral supplement formulated for children. EFA supplements containing gamma-linolenic acid (GLA)(Omega 6) and docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA)(Omega 3) are recommended if the child is not eating oily fish 3 times a week and daily seeds (Holford, 2004 pg 361-365). A properly balanced diet aids in the development of healthy brain cells and healthy cellular functioning. It is important to ensure that the child has no deficiencies and it is advisable to remove as many processed and unnatural substances as possible from the

diet. This will eliminate any dietary contributions to behavioural problems and hyperactivity (Lesperance, 2006).

Further investigation by means of nutritional studies, need to be conducted in order to establish the validity of the role of nutrition in the treatment of AD/HD. It is imperative that the scientific community puts greater effort in developing natural, effective treatments for AD/HD. Results of a double-blind, placebo-controlled study on the efficacy of pine bark extract (Pycnogenol), showed promising results, with a significant improvement in symptoms of hyperactivity, poor attention, visual-motor coordination, and concentration in the treatment group (Barclay, 2006). More effort must be directed towards such studies.

## **2.8 MEASUREMENT TOOLS**

Rating scales usually consist of a list of the DSM-IV criteria symptoms, rated by an observer according to frequency of occurrence. AD/HD rating scales are widely used, and are relevant, and convenient for clinicians. They are valuable as they standardise the assessment of diagnostic symptoms (Kronenberger, 2000 pg 57). On the other hand, current assessment scales fail to assess and fully gauge the effect that AD/HD and its treatment have on everyday quality of life for the child and the family (Landgraf *et al*, 2002). Thus they do not incorporate a holistic view of the impact of the condition on the child and its environment.

It is best to use an existing scale that has credibility and uniformity. Questionnaires must not be too elaborate. School questionnaires give insight into the academic, social and behavioural history of the child from the school's perspective (Levin, 2001). Child questionnaires are not always utilized in studies, as the child is usually the last to notice any improvement in his/her condition (Picton, 2005). In this study both parent and teacher scales have been utilised.



### **2.8.1 ADHD RATING SCALE-IV**

The ADHD Rating Scale-IV scales (Appendices B and C) consist of both Home and School Versions. These rating scales use the diagnostic criteria as listed in the DSM-IV as their basis (Low, 2008). Both the parent/guardian and the child's teacher complete the relevant scales. AD/HD is defined as being present in more than one setting so true assessment must be over two settings, in this case, home and school (Levin, 2001). Thus the ADHD Rating Scale-IV scales are credible, commonly utilized scales for AD/HD screening, diagnosing, treatment monitoring, and research. They are both a tool for diagnosing AD/HD in children and adolescents ages 5-17, and for measuring improvements with treatment. These scales contain 18 items and take 10-20 minutes to administer (School Psychiatry Program & Resource Center, 2008). The parent's questionnaire asks the parents/guardians to rate children's behaviour on a scale of "never" to "very often" and includes questions on activity levels, ability to finish work, forgetfulness and inattention. The teacher's version includes questions on organisation, activity level, disruption to the classroom, listening, and inattention (Low, 2008). The ADHD Rating Scale-IV was utilised in this study due to its credibility and affordability.

### **2.9 PROGNOSIS**

The economic, educational, social and personal costs of AD/HD can be significant (Meyer *et al*, 2004). Once children with AD/HD enter school, a major social burden is placed on them that will last for at least the next 12 years. Up to 30-50% of these children may be retained in a grade at least once and as many as 35% may fail to complete high school altogether. It is a major area of impact of the disability and may create the greatest source of distress for the child and parents (Barkley, 2005 pg 24, 114).

Uninhibited behaviour results in impairment in how well rules, instructions and a child's inner voice or 'conscience' helps that child to control behaviour. For 50% of AD/HD children, social relationships are seriously impaired, and for more than 60%, seriously defiant behaviour leads to resentment by siblings,

frequent scolding and punishment, and a greater potential for delinquency (Barkley, 2005 pg 24, 25, 41). They are at a higher risk for early onset cigarette smoking, and alcohol and drug abuse (Wilens, 2008). Adolescents may become sexually active at an earlier age and may be less likely to employ birth control when they do so. The antisocial behaviour and crime must be taken into account as greater than 20% of children with AD/HD have set serious fires in their communities, 30% have engaged in theft, and 25% are expelled from high school because of serious misconduct. Fighting with other children is a problem for at least 25% of these children (Barkley, 2005 pg 115, 116).

A study conducted by Mannuzza, Klein, Abikoff & Moulton (2004) investigated whether low to moderate levels of childhood oppositional defiant disorder (ODD) and conduct disorder (CD) behaviours contribute to the development of clinically diagnosed CD in adolescence, in children with AD/HD. Participants consisted of 207 white boys, aged 6-12, with AD/HD free of CD. They were assessed at the start of study (aged 6-12) then again at adolescence (mean age 18), with a final follow-up at adulthood (mean age 25). The findings of the study showed that childhood AD/HD, even in children free of antisocial and oppositional behaviours, is a developmental precursor for conduct disorder in adolescence and antisocial behaviour in adulthood (Mannuzza *et al.*, 2004).

Up to 80% of school-aged children given a clinical diagnosis of AD/HD will have the disorder persisting into adolescence, and 30%-65% will have it into adulthood (Barkley, 2005 pg 112). It is seen as a chronic condition continuing into adulthood in approximately half of childhood cases (Wilens, 2008). Adolescents and adults who overcome their symptoms are diagnosed as being "In Partial Remission." This reflects the view that people do not outgrow this disorder but learn to compensate so that the AD/HD symptoms are no longer disabling (Sonna, 2005 pg 3), thus AD/HD in adults is always a continuum of the childhood condition. Adult-onset symptoms are likely due to

other factors. Diagnosing adult AD/HD can be difficult since hyperactivity typically decreases as children get older, whilst attention and organizational problems may be more prominent. As of 2005, it was estimated that AD/HD affects approximately 4.1% of adults aged 18-44 years (ADHD In-Depth Report, 2008 pg 1, 3). It may cause educational as well as interpersonal problems (Wolfe, 2005 pg 467) and even though many of these adults will be employed and self-supporting, their educational level and socio-economic status tend to be low, even when compared to those of their own siblings (Barkley, 2005 pg 116). Between 19-37% of adults with AD/HD have co-existing depression or bipolar disorder; between 25-50% have an anxiety disorder, and approximately 20% of these adults have learning disorders, usually dyslexia and auditory processing problems (ADHD In-Depth Report 2008 pg 3). Only 10-20% of children with AD/HD reach adulthood without any other psychiatric diagnosis, coping well and without significant symptoms of their disorder (Barkley, 2005 pg 116). Untreated adult AD/HD leads to under-functioning even if the person has average to above average intelligence (Picton, 2005 pg 120). On the other hand, many people with AD/HD are able to channel their energy in a positive direction and many of the world's highly successful people have been found to have the condition (Macnair, 2005).

Once AD/HD has developed, how severe it becomes and how much it persists is partly related to how the condition is managed. Failure and under-achievement are likely to dominate the life of a child whose AD/HD is left unrecognised and untreated (Barkley, 2005 pg 24, 25, 106, 107).

## **2.10 HOMOEOPATHY**

Homoeopathy is a medical art and science developed by Samuel Hahnemann. The word 'homoeopathy' is derived from the Greek words *homeos*, meaning 'like' or 'similar', and *pathos*, meaning 'suffering'. The foundations of homoeopathy are the Law of Similars and the infinitesimal dose (De Schepper, 2006).

### **2.10.1 THE VITAL FORCE**

The entire concept of health and healing, according to homoeopathy, is based on the Vital Force, or the energy force within the body. The role of homoeopathy is to reduce the patient's susceptibility to external and internal factors, by strengthening the Vital Force through the application of homoeopathic remedies. Remedies achieve this by stimulating the Vital Force (De Schepper, 2006).

### **2.10.2 THE LAW OF SIMILARS**

This is the principle that a substance, which produces certain symptoms in healthy people, can cure the same symptoms in the sick. In order to cure gently, rapidly, certainly and permanently in each case, one must choose that medicine which can arouse a similar suffering to the one it is supposed to cure (De Schepper, 2006 pg 26).

### **2.10.3 INFINITESIMAL DOSE**

The infinitesimal dose is based on the idea that much smaller doses of a drug are needed to bring about a reaction in the diseased body, as homoeopathy is based on the paradigm of healing that the patient brings about the cure after remedies stimulate the patient's curative powers. This is achieved by administering remedies that are in highly diluted, potentized form, where almost no molecules of the original medicine are present. These remedies are prescribed in a number of different potency scales which all act differently on the organism. The potency is selected according to the clarity of the case and the state of the patient's vital force (De Schepper, 2006 pg 39).

### **2.10.4 TOTALITY OF SYMPTOMS**

The totality of symptoms is a comprehensive picture of the whole person (Reichenberg-Ullman & Ullman, 2000 pg 288). The role of the homoeopath is to find the totality of symptoms through careful, thorough case-taking. This

involves taking into account mental, emotional and physical states of the patient in their current state (De Schepper, 2006).

#### **2.10.5 HOMOEOPATHIC SIMILLIMUM**

The physician must find the remedy that is most similar to the totality of symptoms. This remedy is known as the simillimum and should cover the case on all levels; mental, emotional and physical. Treating with homoeopathic simillimum is the basis of classical homoeopathy. This also brings in the classical homoeopathic concept of the administration of single, simple medicines, as emphasised by Hahnemann in Aphorism 273 (O'Reilly, 2001 pg 246):

*“In no case is it necessary to employ more than a single simple medicinal substance at one time with a patient.”*

#### **2.10.6 HOMOEOPATHIC TREATMENT OF AD/HD**

Homoeopathy provides a valuable service in the treatment of AD/HD (Picton, 2005) as one of the most fundamental tenets of homoeopathy is that we do not treat a disease, but rather a patient with a disease (De Schepper, 2006). A homoeopath observes and explores a child's thought processes, emotional state, physical aspects and nutritional status (Picton, 2005). Advantages of homoeopathy over some drug treatments are the easy administration of the treatment, there is a continuous treatment effect over 24hrs, and there is no risk of abuse (Frei & Thurneysen, 2001 pg 187). Homoeopathic medicine is non-toxic and is not known to produce iatrogenic side effects. Homoeopathic prescribing is not easy, as the remedy of choice must correspond to the patient as well as the illness being treated. (Jack, 2001 pg 11, 30)

## **2.11 HOMOEOPATHIC RESEARCH ON AD/HD**

Lamont (1997) conducted research into the homoeopathic treatment of AD/HD using simillimum. He conducted the study on 43 children diagnosed with AD/HD. They were assigned placebo or homoeopathic simillimum in a double-blind, partial crossover study to test the efficacy of the treatment for this disorder. Medication was administered in the 200CH potency. Statistical analysis was based on parent or caregiver ratings before and after treatment. A 5-point rating scale was utilized. The placebo group only received placebo for the first 10 days of the study, thereafter they proceeded with simillimum treatment. The comparison results for the initial placebo group versus the initial treatment group were mean improvement scores of 0.35 for the placebo group and 1.00 for the treatment group. At the follow-up interviews, 2 months after treatment was completed, of those that showed improvement on homoeopathic treatment, 57% had continued improvement, 24% showed improvement for several days or weeks after treatment but had relapsed before the follow-up, and the remaining 19% only had improvement whilst on the homoeopathic medication. The results of this study thus showed homoeopathic treatment to have greater efficacy in the treatment of this disorder than placebo. This study has decreased credibility due to the fact that the placebo group was known to the researcher, introducing the possibility of him inadvertently influencing the outcomes, and that it was not maintained as a placebo group as the participants were given treatment after 10 days. An accredited rating scale was not utilised. The researcher also limited the treatment to one potency. In the current study the researcher remained blinded throughout the study, there remained a placebo group for the duration of the study, an accredited rating scale was utilised, and simillimum treatment was not limited to a specific potency. It was administered in the potency most indicated by the individual case.

Frei and Thurneysen (2001) conducted a study comparing homoeopathy and methylphenidate in a family setting on 115 hyperactive children, aged 3-17 years. Each participant had to have a predetermined level of severity of hyperactivity, measured by Conners' Global Index (CGI), and each received

individual homeopathic treatment in LM potency. Once overall clinical improvement, summarised as a percentage by the parents, reached 50%, symptoms were re-evaluated. Those participants whose CGI had not improved sufficiently were changed to methylphenidate and re-evaluated after 3 months. After an average treatment time of 3.5 months, 75% of the participants had responded to homeopathic treatment, with a clinical improvement of 73% and a decrease in the CGI of 55%. Methylphenidate was administered to 22% of the children, with clinical improvement of 65% and a decrease in the CGI of 48%. Three children did not respond to either treatment. The parent ratings of clinical improvement and the CGI scores were slightly better under homeopathic treatment than under methylphenidate. An interesting observation in this study is that in the intervals between homeopathic medicines the children displayed a reappearance of hyperactivity symptoms, favouring the impression that homeopathy is more of a palliative treatment for AD/HD. Long-term follow up studies would be required in order to ascertain whether a curative effect can be expected (Frei & Thurneysen, 2001 pg 186). Only LM potencies were utilised in the current study.

Frei, Everts, von Ammon, Kaufmann, Walther, Hsu-Schmitz, Collenberg, Steinlin, Lim & Thurneysen (2007) conducted another study; this time a randomised, placebo-controlled, cross-over trial on 83 children with AD/HD. The Swiss study was designed with an open-label screening phase prior to the randomised controlled phase. During the screening phase the response of each child to successive homeopathic medications was observed until the optimal medication was identified. Eighty four percent of the children responded to treatment to a degree that they became eligible for the randomised trial. Only children who reached a predefined level of improvement participated in the randomised, cross-over phase. The double-blind part of the study consisted of two groups of children who received either simillimum treatment for 6 weeks followed by placebo, or placebo for 6 weeks followed by treatment. A significant difference between placebo and treatment was displayed, showing that the effects of homeopathy are specific and

cannot be attributed to placebo. However, two problems were encountered. There was a strong carry-over effect and an unexpected rise in the rating scale readings in the treatment group during the first cross-over period. These were attributed to parental expectation that their child would receive placebo during this period. These problems reduced the size of the apparent treatment effect and could have been avoided had randomisation and closed labels been implemented at treatment start (Frei *et al*, 2007, 35-41). Other factors in this trial are that only LM potencies were utilised and only a 10-item rating scale was used to monitor treatment.

In terms of South African homoeopathic studies, Middleborough (2004) conducted a study to determine the efficacy of supplementation using Evening Primrose Oil and Low Homoeopathic Potency Gamma Linolenic Acid (GLA) in the management of ADD and ADHD in boys. His results showed that there was no statistical significant improvement within the individual scores of the treatment groups. It was however apparent that there was an improvement with regards to the mean scores of the Evening Primrose Oil group, and to a lesser extent, the Homoeopathic GLA group, indicating slight improvement in the participants of these 2 groups. Lottering (2006) conducted a study to establish the efficacy of Advanced Brain Food® and a Homoeopathic complex, Quietude® (Nux moschata 4C, Hyoscyamus niger 3X, Passiflora incarnata 3X and Stramonium 6X) in the management of AD/HD in boys. Using the ADHD Rating Scale-IV, the intra-group comparison of the results of each of the groups showed no statistically significant improvement within the individual scores. Inter-group comparison however revealed that there was improvement in the mean scores of the Advanced Brain Food® group, and to a lesser extent, the Quietude® group. This indicated a slight improvement (not statistically significant) in the participants of these 2 groups. Thus, to date, no studies have investigated the effects of homoeopathic simillimum in the treatment of AD/HD in the South African context, emphasising the importance of this study in the development of the treatment of AD/HD using homoeopathic simillimum in this country.



## **CHAPTER 3: MATERIALS AND METHODS**

### **3.1 STUDY DESIGN**

The objective of this study was to determine the relative efficacy of homoeopathic simillimum in the treatment of AD/HD in schoolgoing children aged 6-11 years. This was a clinical trial in which an experimental group was compared to a placebo control group. The study was conducted as a double-blind study. The 40 participants were randomly divided into 2 groups prior to the study.

Group 1 was the treatment group receiving homoeopathic simillimum.

Group 2 was the control group receiving placebo.

The study required 3 consultations at The Homoeopathic Day Clinic with the researcher. These took the form of an initial consultation and 2 follow-up consultations. The consultations were spaced 4 weeks apart. The parent/guardian and the participant had to be present at each of these. A homoeopathic case history (Appendix I) was taken at the initial consultation and a physical exam (Appendix J) was performed at each consultation. The purpose of the consultations was to find the simillimum for each case. After each consultation the case was analysed using Radar 9.0 Repertory Programme for Windows to find the simillimum (Appendix N). A treatment protocol was formulated for each child and this was confirmed by 1 of 2 specified clinicians of The Homoeopathic Day Clinic. The script was then forwarded to a technician for dispensing.

Results were captured by means of the ADHD Rating Scale-IV. Both the Home and School Versions were utilized (Appendices B and C). These were completed by the parent/guardian and teacher respectively. The parent/guardian completed the Home Version at each consultation. The School Version was sent to school, and was completed by the teacher before

treatment commenced and again just before each follow-up consultation. Only subjective data was incorporated in the analysis.

### **3.2 LOCATION OF STUDY**

The trial was conducted at The Homoeopathic Day Clinic at The Durban University of Technology (DUT). Permission to utilise the clinic was granted by the Clinic Director.

### **3.3 ADVERTISING AND RECRUITMENT**

Advertisements were placed in local Durban newspapers (Appendix L). These advertised free homoeopathic treatment for children with AD/HD. Advertisements were put up at DUT, local libraries, schools, shopping centres, community boards, health shops and pharmacies (Appendix M). Schools were approached and talks on the subject of AD/HD and this research study were given. An article (Appendix K) about the study was placed on the ADHASA Website, with permission from the site co-ordinator ([www.adhdasa.co.za](http://www.adhdasa.co.za)).

Forty participants were recruited as a result of these advertisements, by means of convenience sampling. A minimum of 30 participants were required for statistical analysis but the researcher had to allow for drop out. A total of 10 participants dropped out of the study or failed compliance, resulting in a final sample group of 30 participants.

### **3.4 SELECTION CRITERIA**

Parents/guardians who called in response to the advertisement underwent a telephonic discussion (Appendix D). This discussion was based on clear inclusion and exclusion criteria (see below) to determine whether their child was a suitable candidate for the study. This was assessed by the following criteria:

Inclusion criteria:

- Participants had to be between the ages of 6-11 years at the start of the study.
- Participants had to be fluent in English due to limitations of the language versions of the scales used and limitations in case-taking.
- Participants had to be pre-diagnosed with AD/HD by a child psychologist or paediatrician.
- Participants had to fulfil diagnostic criteria for 314.00 Attention Deficit/Hyperactivity Disorder, Combined Type, 314.00 Attention-Deficit/Hyperactivity Disorder, Predominantly Inattentive Type, or 314.01 Attention-Deficit/Hyperactivity Disorder Predominantly Hyperactive-Impulsive Type according to DSM-IV (Appendix A).

Exclusion criteria:

- A child who was currently taking medication, orthodox or natural, for AD/HD. Children taking any treatment for AD/HD had to cease treatment 1 week prior to commencing the study and abstain from treatment for the duration of the study.
- A child who was on chronic medication for another condition (e.g. Insulin for diabetes; steroids for chronic asthma).
- Children with other known mental or behavioural disorders, as diagnosed by a child psychologist or paediatrician (e.g. mood disorder, bipolar disorder, conduct disorder or oppositional defiant disorder)

If the child fulfilled the selection criteria the parents/guardian were briefed on further details of the study and, if willing to participate, were scheduled an initial consultation. At the initial consultation the parent/guardian and child received subject information letters (Appendices E and G) with more detailed information about the study and were afforded the opportunity to ask questions with regards to the study. When both the parent/guardian and the

child agreed to participate in the study they were given informed consent and assent forms (Appendices F and H) respectively, which had to be completed and signed. Parents/guardians and participants were informed that they could withdraw from the study at any point, without giving reasons.

### **3.5 SAMPLE GROUP**

Out of the 40 participants, 10 dropped out of the study. Thus the final sample group consisted of 30 participants. The sample was chosen by means of the convenience sampling method, whereby any participant who fulfilled the aforementioned criteria and was able to be compliant during the study period, was accepted. The advertisements were not targeted at any particular racial group or demographic. They covered a varied income and racial preponderance. Of the total group, 17 were Asian, 12 were Caucasian, and 1 was African.

Participants who conformed to the afore-mentioned criteria, had been briefed on the necessary details of the study, and had signed the informed consent and assent forms (Appendices F and H) were included in the study sample group.

### **3.6 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 parent/guardian would know which group they had been assigned to. The researcher only had access to this list once all participants had completed the trial. The list consisted of a sheet with numbering 1-40. Each number was randomly allocated either treatment or placebo. As each new participant entered into the trial they were assigned, in numerical order, a participant number, which would correlate to a number on the randomisation sheet and either treatment or placebo would be dispensed accordingly.

### **3.7 INTERVENTION**

The technician prepared the medication in The Homoeopathic Day Clinic, dispensary according to the German Homoeopathic Pharmacopoeia (British Homoeopathic Association, 1978).

Each participant received 3 powders and/or a 25ml bottle of drops. Active treatment was indistinguishable from placebo.

Treatment consisted of centesimal (CH) potencies, plussed potencies and quinquagenimillesimal (LM) potencies. The choice of potency and posology was determined for the individual participant, according to their requirements.

The homoeopathic dispenser prepared the powders as per method 10, according to the Pharmacopoeia, which is as follows: Active ingredient (i.e. the medication) was added to the powders. The powders consisted of fine lactose with added lactose granules. The method of medication of the powders was by impregnation of 1% v/v of approximately 10 granules per sachet with simillimum in 96% ethanol. The placebo powders were impregnated with unmedicated 96% ethanol, as per the method above. The placebo powders were indistinguishable from the medicated powders (British Homoeopathic Association, 1978 pg 39).

The plussed potencies were prepared as per method 8, which is as follows: 10 granules, of either the remedy-impregnated granules or the neutral granules, were placed in a 25ml dropper bottle. 18ml of water was added after which the bottle was swirled to dissolve the granules. 2.5ml of 96% ethanol was added to the bottle once the granules completely dissolved. The bottle was then closed and vigorously shaken 10 times (British Homoeopathic Association, 1978 pg 38).

The LM potencies were prepared as per method 17, which is as follows: 1 remedy-impregnated granule or 1 neutral granule was placed in a 25ml dropper bottle. The granule was dissolved in 18ml of distilled water, after which 2ml of 96% ethanol was added (British Homoeopathic Association, 1978 pg 45, 46).

Participants took 3 powders each day for 3 consecutive days and/or drops were taken on a daily basis and continued, according to the instructions on the dropper bottle.

The dispenser dispensed the relevant medication according to the randomisation list.

### **3.8 MEASUREMENT TECHNIQUE**

The ADHD Rating Scales-IV (Appendices B and C) was utilized in this study. They were completed by the parent/guardian and teacher.

#### **3.8.1 ADHD RATING SCALE-IV**

The questionnaires are based on the diagnostic criteria for AD/HD as described in the fourth edition of The Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR, 2000). The Home and School Versions of the ADHD Rating Scale-IV were utilized (Appendices B and C).

The ADHD Rating Scale-IV is a tool both for diagnosing AD/HD in children and adolescents ages 5-17 and for measuring improvements with treatment. These scales contain 18 items and take 10-20 minutes to administer (School Psychiatry Program & Madi Resource Center, 2008). The 18 scale items were written to reflect DSM-IV criteria as closely as possible whilst maintaining brevity (DuPaul, Power, Anastopoulos & Reid, 1998).

The DSM-IV provides diagnostic criteria organized into 2 dimensions of Inattention and Hyperactive-Impulsive, each of which consists of 9 symptoms, which are equally represented on the questionnaire (DuPaul et al., 1998). Thus both versions of the scales consist of 2 subscales that are empirically derived and conform to the 2 symptomatic dimensions described in the DSM-IV. Therefore 3 scores (Inattention, Hyperactivity/Impulsivity, and Total) can be derived from each version. Raw scores can also be converted into percentile scores by using the appropriate scoring profile based on the child's gender and age (DuPaul et al., 1998). For the purposes of this study these percentile scores, as well as the raw scores, were considered for statistical analysis.

AD/HD is defined as being present in more than one setting so true assessment must be over two settings, in this case, home and school. The questionnaires ask the parent/guardian and teacher to rate the child's behaviour on a scale of "never" to "very often" and include questions on activity levels, ability to finish work, forgetfulness, inattention, organisation, listening and inattention (Low, 2008).

To ensure the full co-operation of parents/guardians and teachers, questionnaires should not be too elaborate and cumbersome (Levin, 2001). Thus the ADHD Rating Scale-IV was utilized, as it consists of credible, commonly used scales for ADHD screening, diagnosing, treatment monitoring, and research.

During the course of the study 3 copies of each of the Home and School Versions were completed (Appendices B & C). The Home Versions were completed by the same parent/guardian at each consultation to ensure reliability of data. The School Versions were sent to school for the class teacher to complete. Thus the questionnaires were completed at 4-week intervals.

Child questionnaires were not utilized in this study, as the child is usually the last to notice any improvement in his/her condition (Picton, 2005).

### **3.9 DATA ANALYSIS**

The data required for this study consisted of the parents/guardians and teacher's subjective observations of the participant's behaviour before, during and after the study. The general perceptions of the treatment from the parent/guardian, teacher and child were also considered as qualitative results. The subjective data was made up of the score symptoms from the ADHD Rating Scale-IV. The score of symptoms was further subdivided into 3 variables, namely Inattention, Hyperactivity-/Impulsivity, and Total score, being a sum of the 2 variables. The statistical analysis was conducted using SPSS® for Windows™ (Version 17.0) and Excel® XP™.

For the quantitative statistics, raw data was analysed using inferential statistics, namely Wilcoxon's Signed Rank Test (This compared the treatment and placebo group independently of each other across different time periods). Further the Reliable Change Index (RCI) was calculated for each component and for each assessment period. This was calculated by dividing the difference between two assessments by the standard error of observation. The RCI is a measure of the clinical significance of an observation rather than a statistical significance. It returns the value of the observations, given the age and gender of the subject being assessed as well as the component being assessed. This is a reflection of an adjustment for observer error, not sampling error or population differences. Raw data as well as the RCI's were used in the inferential statistics.

The Intergroup Analysis was conducted using the Kruskal-Wallis-H test and the Mann Whitney U test. These were done using the RCI calculations. Both these tests were used to determine the effect of a factor on the observed results (e.g. dosage form, ethnic group or treatment group).



Barcharts, scatterplots, stem and leaf diagrams and tables were used for the descriptive statistics.

### **3.10 ETHICAL CONSIDERTIONS**

This was a double-blind, placebo-controlled study. AD/HD is not a life-threatening condition. The parents/guardians and children participating in the study were informed of the possibility that they may receive placebo before the trial began. Bearing this in mind the researcher considered it ethically acceptable to utilize a placebo group as a measure against which treatment could be compared. On completion of the study those in the placebo group were informed and offered free treatment.

## **CHAPTER 4: RESULTS**

### **4.1 INTRODUCTION**

Following the methodology described in Chapter 3, the study produced raw data in the form of completed assessment score sheets (both Home and School Versions). Each subject was assessed three times, once initially, once on first follow up and once at final follow up. Each subject therefore had 6 score sheets representing behaviour assessments over the course of the trial.

The specific objectives of the analysis were as follows:

- (1) To describe the demographic characteristics of the subject group.
- (2) To determine any statistically significant differences between the placebo and treatment groups with respect to demographic variables.
- (3) To determine any statistically significant correlations between the responses on the Home and School Versions of the scale for both placebo and treatment groups.
- (4) To determine any statistically significant changes in the severity of the subjects' symptoms (as measured by the Home and School Versions of the scale) for both treatment and placebo groups.
- (5) To determine any statistically significant differences between the treatment and placebo groups with respect to treatment outcomes (as measured by the Home and School Versions of the scale).

The analysis of the data was done using SPSS® for Windows™

(Version 17.0) and Excel® XP™.

## **4.2 OVERVIEW OF RESULTS CHAPTER**

### **4.2.1 DESCRIPTIVE DATA**

#### **4.2.1.1 DEMOGRAPHICS**

These comprised distribution tables and graphical depiction of the demographic data (Gender, and Age Category).

#### **4.2.1.2 REMEDY BREAKDOWN**

These comprised distribution tables and graphical depiction of the data related to remedies given in the study (both on initial treatment and follow up).

#### **4.2.1.3 POTENCY BREAKDOWN**

These comprised distribution tables and graphical depiction for the data related to the potencies used in the study (both on initial treatment and follow up).

#### **4.2.1.4 RESULTS**

These comprised graphical summaries of the results of the trial. Results were grouped in a number of ways to illustrate emergent relationships.

Each application of the Rating Scale yielded 6 data sets (4 unique) for analysis. These were Home Version Hyperactivity/Impulsivity, Home Version Inattention and Home Version Total (derived from the addition of scores from the two separate components); School Version Hyperactivity/Impulsivity, School Version Inattention and School Version Total (derived from the addition of the two separate components).

This breakdown of the data into discrete units enabled significantly more analysis than would otherwise have been possible.

#### **4.2.2 ANALYSIS**

Non parametric statistical tests were used to determine the presence and significance of correlations between demographic descriptors, remedy breakdown and potency breakdown with responses to treatment.

Further, non parametric tests were used to determine the presence and significance of correlations between:

- Home and School Versions of the scale for placebo and treatment groups
- Responses to treatment after first and second follow up in both treatment and placebo groups
- Responses to treatment for subjects given different potencies and remedies.

### **4.3 ABBREVIATIONS**

Respondent = individual satisfying inclusion criteria who completed the questionnaire

$H_0$  = null hypothesis

$H_1$  = alternative hypothesis

S.D. = Standard deviation

z = Standardised z value for statistical measurements

p = two tailed probability of equalling or exceeding  $z/2$

N.S. = No statistically significant difference

S = Statistically significant difference

If  $p \leq 0.05$  then a significant difference was concluded (5% level of significance)

If  $p > 0.05$  then no significant difference was concluded (5% level of significance)

4.4 DESCRIPTIVE STATISTICS

4.4.1. DEMOGRAPHICS

The data used for the following analyses were derived from the completed questionnaires. In terms of the objectives described in the introduction, the respondents’ demographic characteristics were described.

Table 4.1 Table showing gender distribution of sample

	Gender	
	F	M
Count	4	26

Figure 4.1 Chart showing gender proportions of the sample

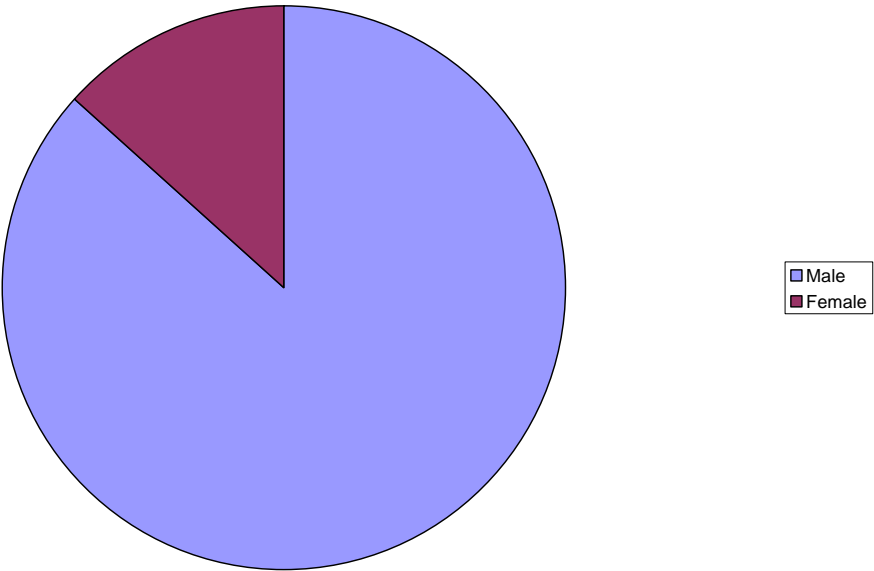
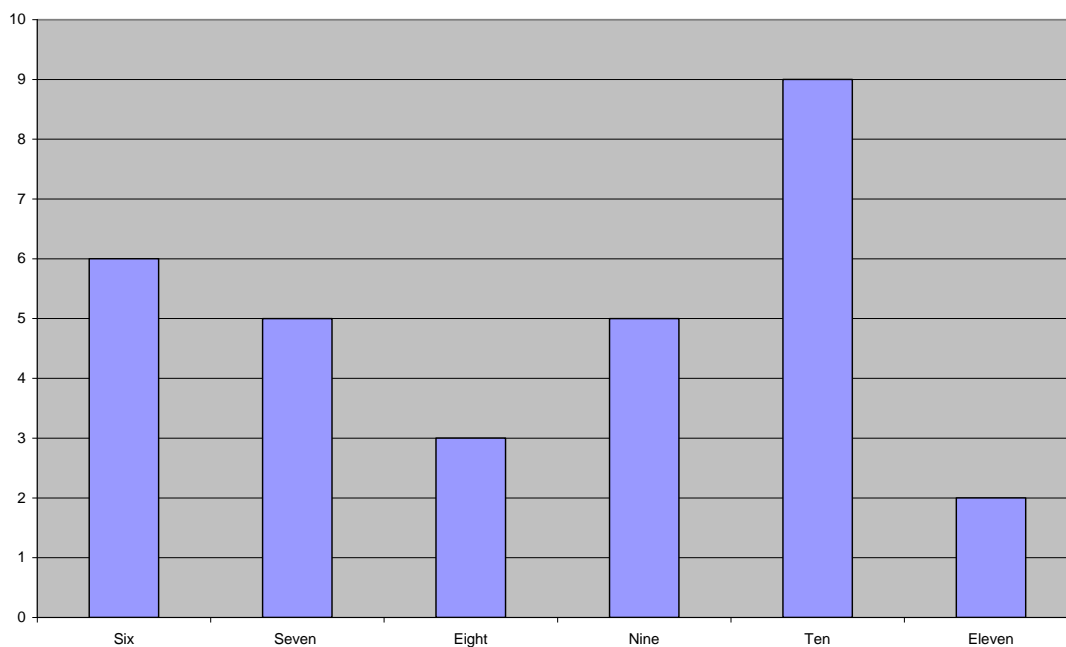


Table 4.2 Table showing age distribution of sample

Age Category	Number of Respondents	Percentage of Respondents
Six	6	20
Seven	5	16.67
Eight	3	10
Nine	5	16.67
Ten	9	30
Eleven	2	6.67

Figure 4.2 Graph showing age distribution of sample



#### 4.4.2 REMEDY BREAKDOWN

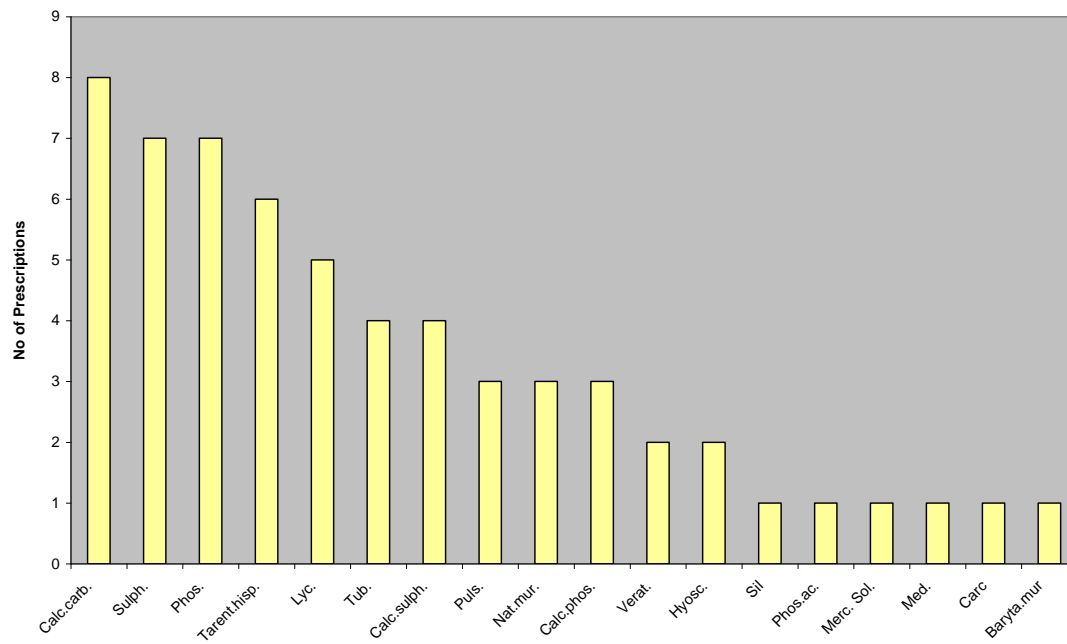
The remedies given (in both initial and follow up consultation) were used to compile the table and graph.

Table 4.3 Table showing breakdown of remedies given

Remedy	First Consultation	Second Consultation	Total
Calc.carb.	4	4	8
Sulph.	3	4	7
Phos.	3	4	7
Tarent.hisp.	4	2	6
Lyc.	3	2	5
Tub.	1	3	4
Calc.sulph.	2	2	4
Calc.phos.	2	1	3
Nat.mur.	2	1	3
Puls.	1	2	3
Hyosc.	1	1	2
Verat.	1	1	2
Sil	1	0	1
Phos.ac.	0	1	1
Baryta.mur	0	1	1
Med.	0	1	1
Merc. Sol.	1	0	1
Carc	1	0	1



Figure 4.3 Graph showing breakdown of remedies given



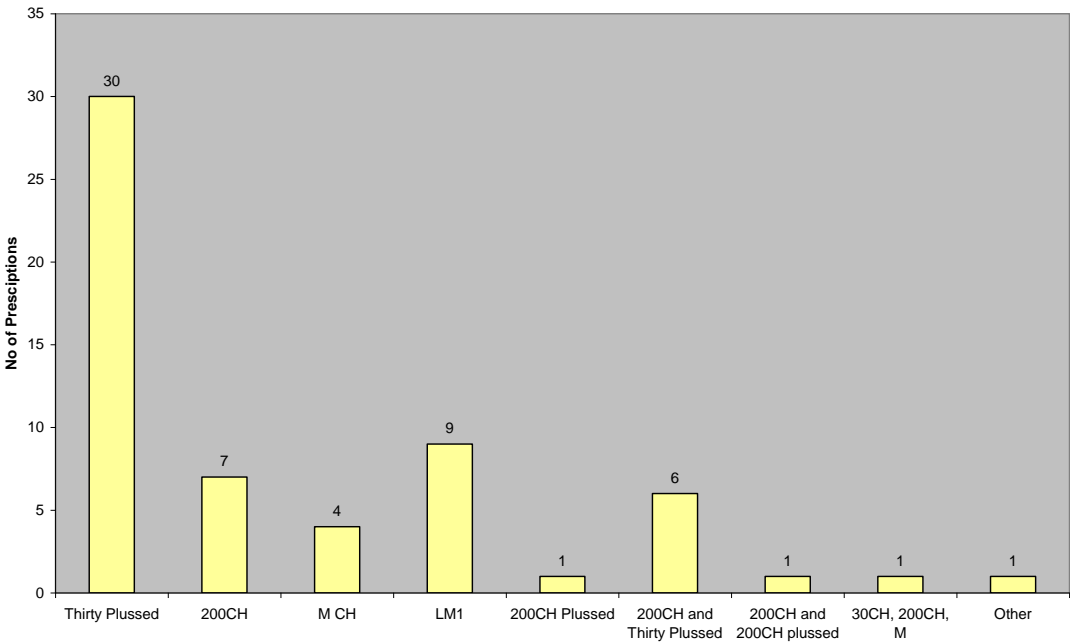
#### 4.4.3 POTENCY BREAKDOWN

The remedies given and the potencies and dosage forms prescribed in (in both initial and follow up) were used to derive the following tables and graphs.

Table 4.4 Table showing breakdown of potencies used

	First Consult	Second Consult	Total
Thirty Plussed	17	13	30
200CH	5	2	7
M CH	3	1	4
LM1	5	4	9
200CH Plussed	0	1	1
200CH and Thirty Plussed	0	6	6
200CH and 200CH plussed	0	1	1
30CH, 200CH, M	0	1	1
Other	0	1	1

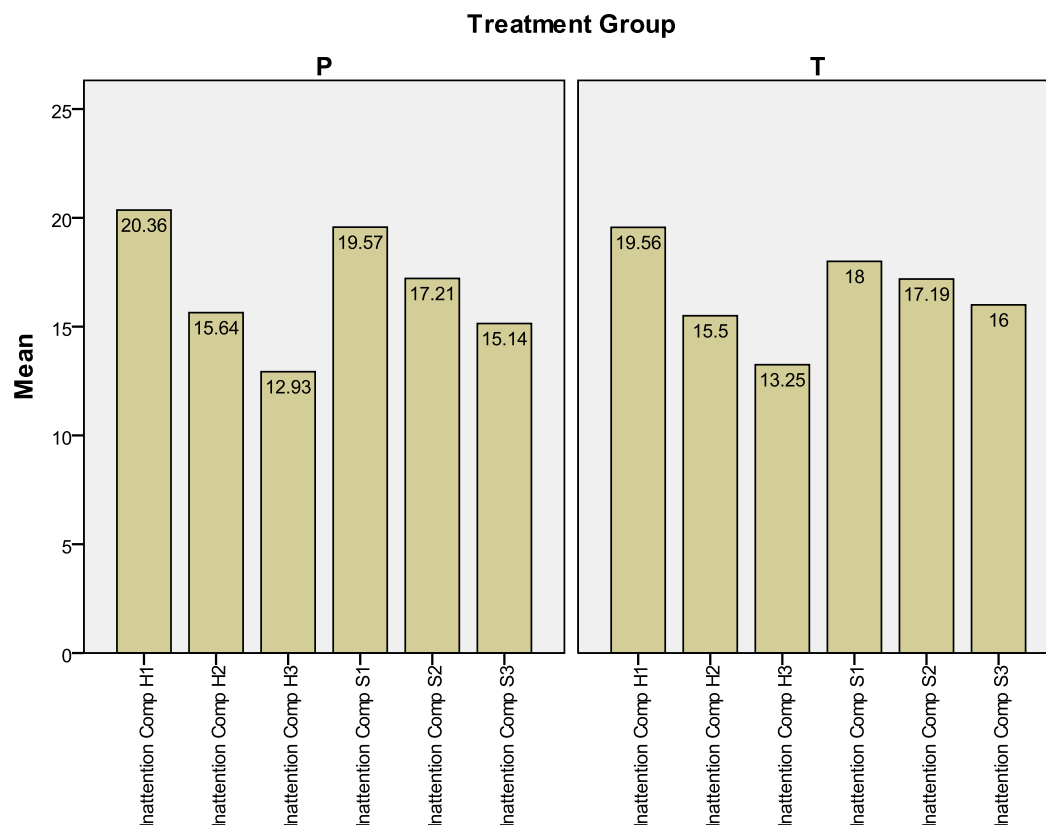
Figure 4.4 Graph showing breakdown of potencies used



#### 4.4.4 RESULTS

The ADHD Rating Scale-IV was applied on three occasions. Each application yielded 6 data sets. The results of the applications are presented as follows.

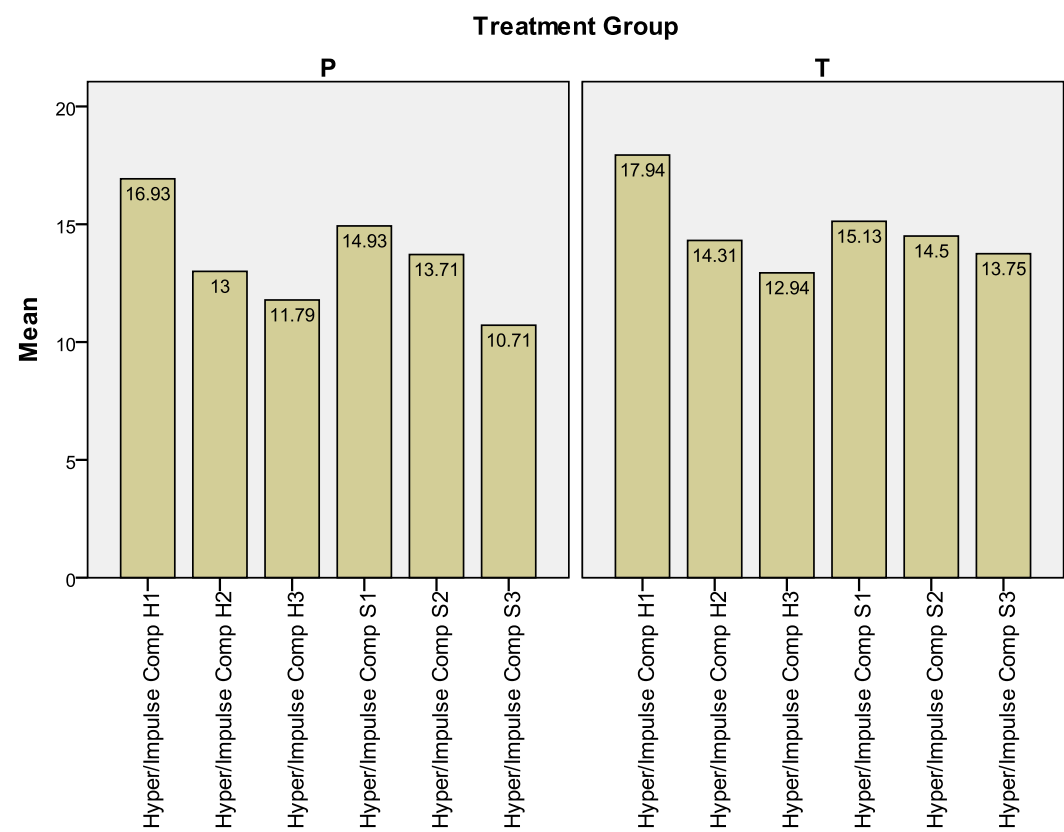
Figure 4.5 Graph showing values of the average scores for the Inattention component of the scale over the three applications (panelled by treatment group)



From the graph above it is apparent that both the treatment and placebo group demonstrated sizeable improvements in symptoms as measured by the ADHD Rating Scale-IV.

In both placebo and treatment groups, the reduction in scores appeared more significant as measured by the Home Version (H1, H2 and H3). This is discussed further in Section 5.2.

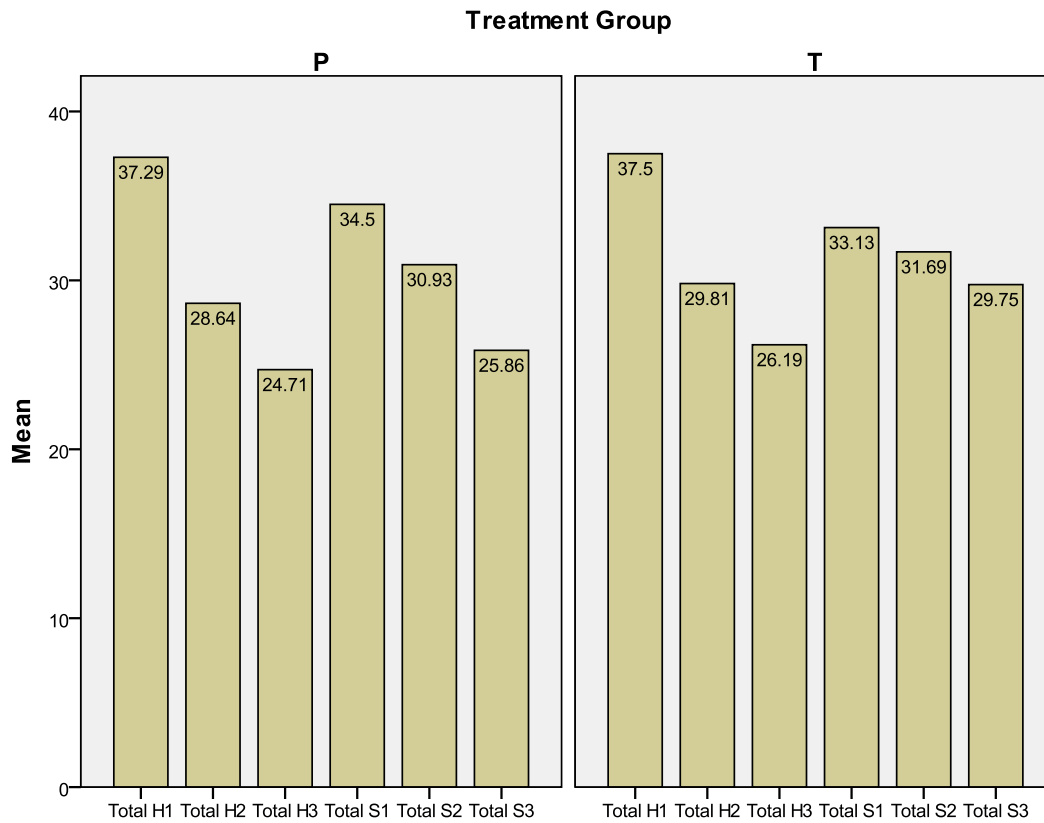
Figure 4.6 Graph showing values of the average scores for the Hyperactivity/Impulsivity component of the scale over the three applications (panelled by treatment group)



Significant reductions in mean scores were observed in both placebo and treatment groups across all applications of the scale.

Again reductions were apparently more marked as measured by the Home Versions of the scale.

Figure 4.7 Graph showing values of the average scores for the scale (Total Measure) over the three applications (panelled by treatment group)



As expected given the component graphs, the above figure reinforces the impression that both placebo and treatment group demonstrated reductions in overall AD/HD score as measured by the ADHD Rating Scale-IV.

The improvements noted on the School Version seem to be less significant than those on the home scale. The statistical significance of this apparent difference will be investigated in section 4.5.

#### 4.5 CORRELATION ANALYSIS

Non parametric statistical tests were used to determine the presence and significance of correlations between demographic descriptors, remedy breakdown and potency breakdown with responses to treatment.

Further, non parametric tests were used to determine the presence and significance of correlations between:

- Home and School Versions of the scale for placebo and treatment groups
- Responses to treatment after first and second follow up in both treatment and placebo groups
- Responses to treatment in treatment and placebo groups after initial and second consultation
- Responses to treatment for subjects given different potencies and remedies.
- Responses to treatment of different ethnic grouping.

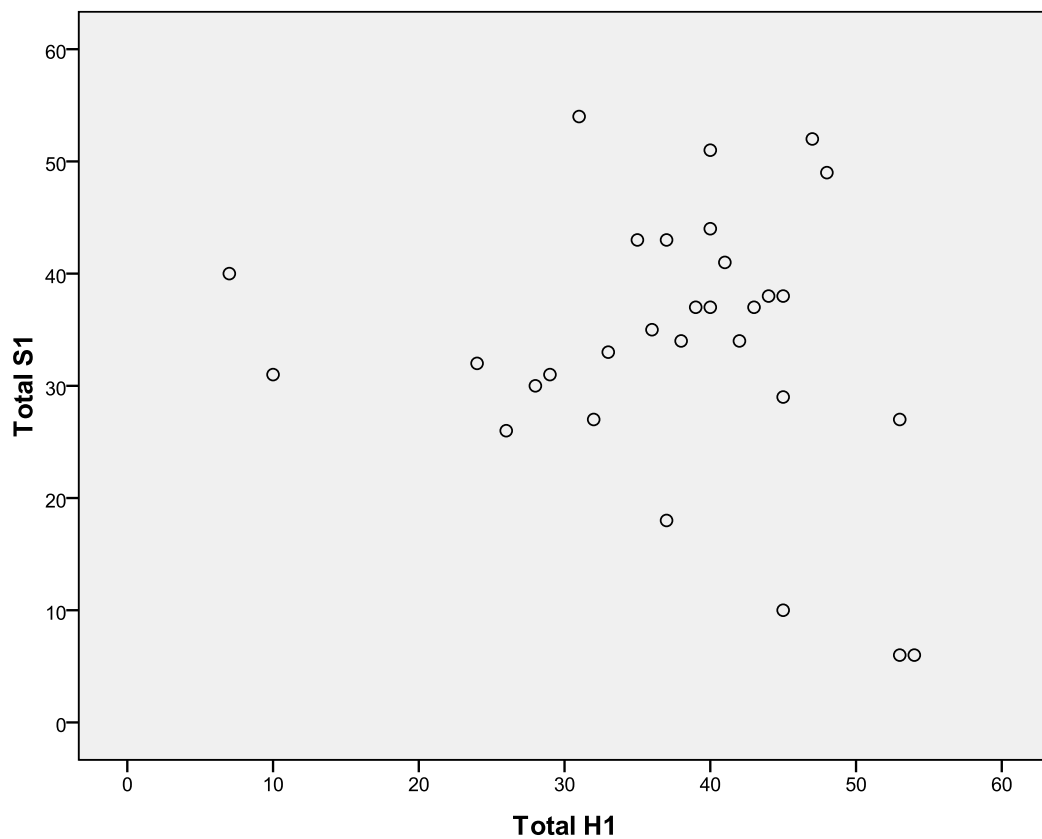
The level of significance was set at 5% i.e.  $p \leq 0.05$ .

#### **4.5.1 CORRELATION TESTING- HOME VS SCHOOL VERSIONS**

As noted in the graphical analyses of the results, the School Version of the scale demonstrated apparently different levels of results. In order to assess the statistical significance of this relationship, correlations between the Home and School Versions of the scale were investigated.

Graphical exploration of the relationship was conducted using scatterplots to assess relationships.

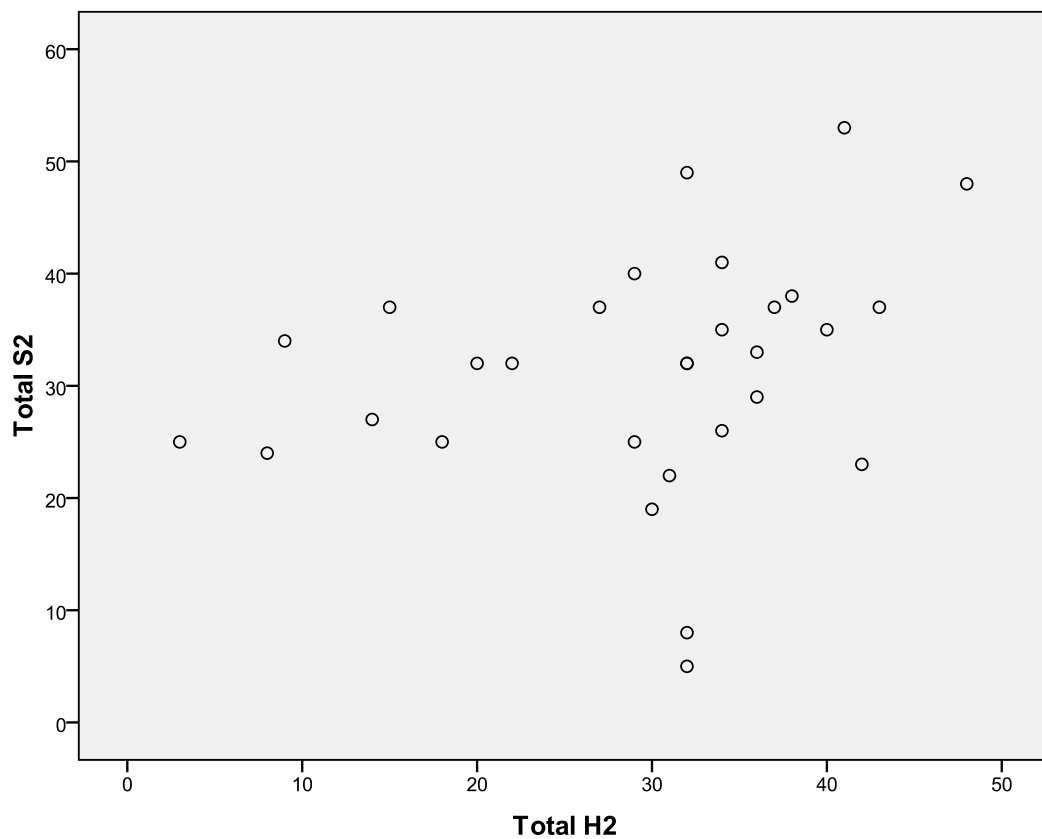
Figure 4.8 Scatterplot showing total scores for Home Version vs School Version rating scales on first assessment



From figure 4.8 above, there is no apparent correlation between scores on the Home Version and School Version of the rating scales at first assessment.

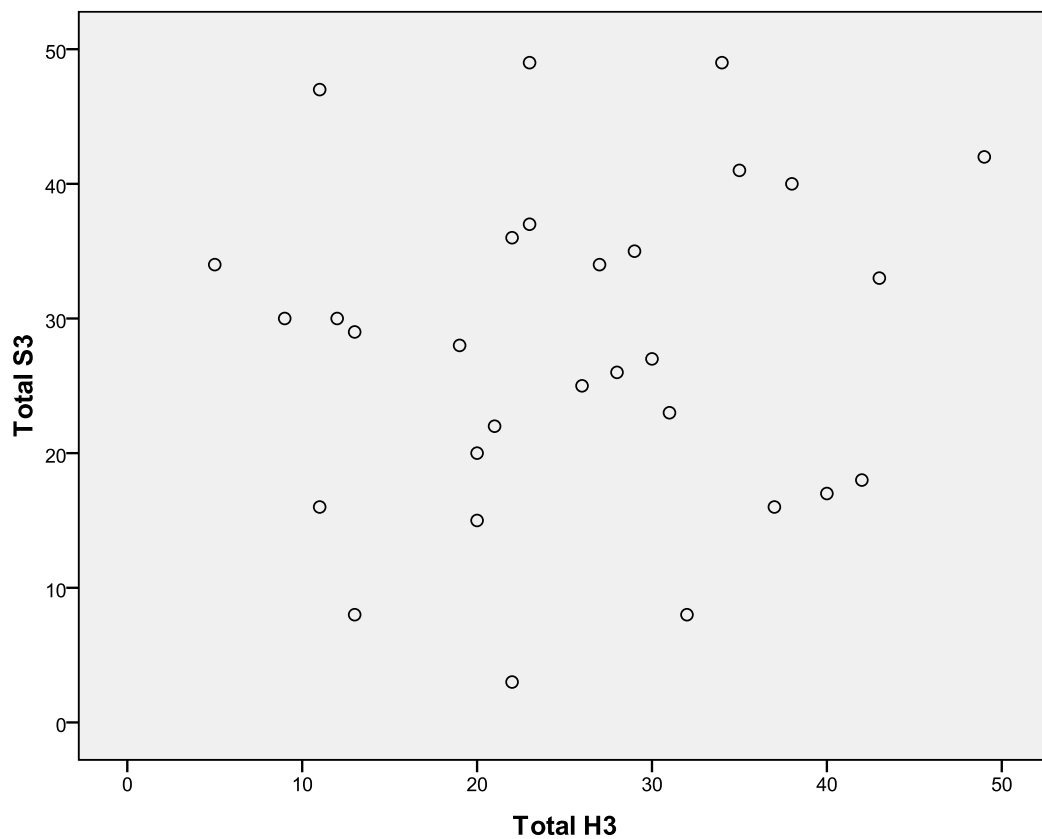


Figure 4.9 Scatterplot showing total scores for Home Version vs School Version rating scales at second assessment.



There is no apparent correlation between scores on the Home Version and School Version of the rating scales.

Figure 4.10 Scatterplot showing total scores for Home Version vs School Version rating scales at third assessment.



There is no apparent correlation between scores on the Home Version and School Version of the rating scales.

Table 4.5 shows the values of the Wilcoxon Signed Rank test used to test the hypothesis that there were no significant correlations between Home and School Versions of the test- the null hypothesis.

Table 4.5 confirms the graphical findings above. There were no significant correlations between Home and School Versions of the rating scale at any of the assessments.

Null hypothesis 1: There was no significant difference between the assessment of a subject using the Home Version and School Version of the rating scale (i.e. both samples are drawn from the same population).

Alternative hypothesis 1: There was a significant difference between the assessment of a subject using the Home Version and School Version of the rating scale.

Due to the ordinal nature of the data and the unknown, possibly non-normal distribution of the data non-parametric statistics were used to test the hypothesis, namely the Wilcoxon Signed Rank test.

Table 4.5 below shows the results of the hypothesis testing for each individual sub-component (i.e. Hyperactivity/Impulsivity or Inattention) compared between School and Home Versions of the rating scale.

Table 4.5 Table showing Z statistic and significance level for Wilcoxon Signed Rank test

Variables compared	Z-Score	Significance Value	Significance
<b>Inattention Comp S1 - Inattention Comp H1</b>	<b>-.370</b>	<b>0.711</b>	<b>N.S.</b>
<b>Inattention Comp S2 - Inattention Comp H2</b>	<b>-1.266</b>	<b>0.205</b>	<b>N.S.</b>
<b>Inattention Comp S3 - Inattention Comp H3</b>	<b>-1.629</b>	<b>0.103</b>	<b>N.S.</b>
<b>Hyper/Impulse Comp S1 - Hyper/Impulse Comp H1</b>	<b>-1.225</b>	<b>0.221</b>	<b>N.S.</b>
<b>Hyper/Impulse Comp S2 - Hyper/Impulse Comp H2</b>	<b>-.320</b>	<b>0.749</b>	<b>N.S.</b>
<b>Hyper/Impulse Comp S3 - Hyper/Impulse</b>	<b>-.054</b>	<b>0.957</b>	<b>N.S.</b>

<b>Comp H3</b>			
<b>Total S1 – Total H1</b>	<b>-.805</b>	<b>0.421</b>	<b>N.S.</b>
<b>Total S2 – Total H2</b>	<b>-1.104</b>	<b>0.270</b>	<b>N.S.</b>
<b>Total S3 – Total H3</b>	<b>-.768</b>	<b>0.443</b>	<b>N.S.</b>

No significant values were returned. The probability of the observed difference in medians being attributable to chance is high enough to explain the observed differences. We therefore accept the null hypothesis: there was no significant difference in the assessment of a subject using the Home or School Versions of the scale.

#### **4.5.2 CORRELATION ASSESSMENT: RESPONSES TO TREATMENT**

From Figure 4.7 it appears that there were significant responses to treatment in both Treatment (T) and Placebo (P) groups. The statistical significance of this observation was assessed using non-parametric and computational methods.

##### **4.5.2.1 RELIABLE CHANGE INDEX**

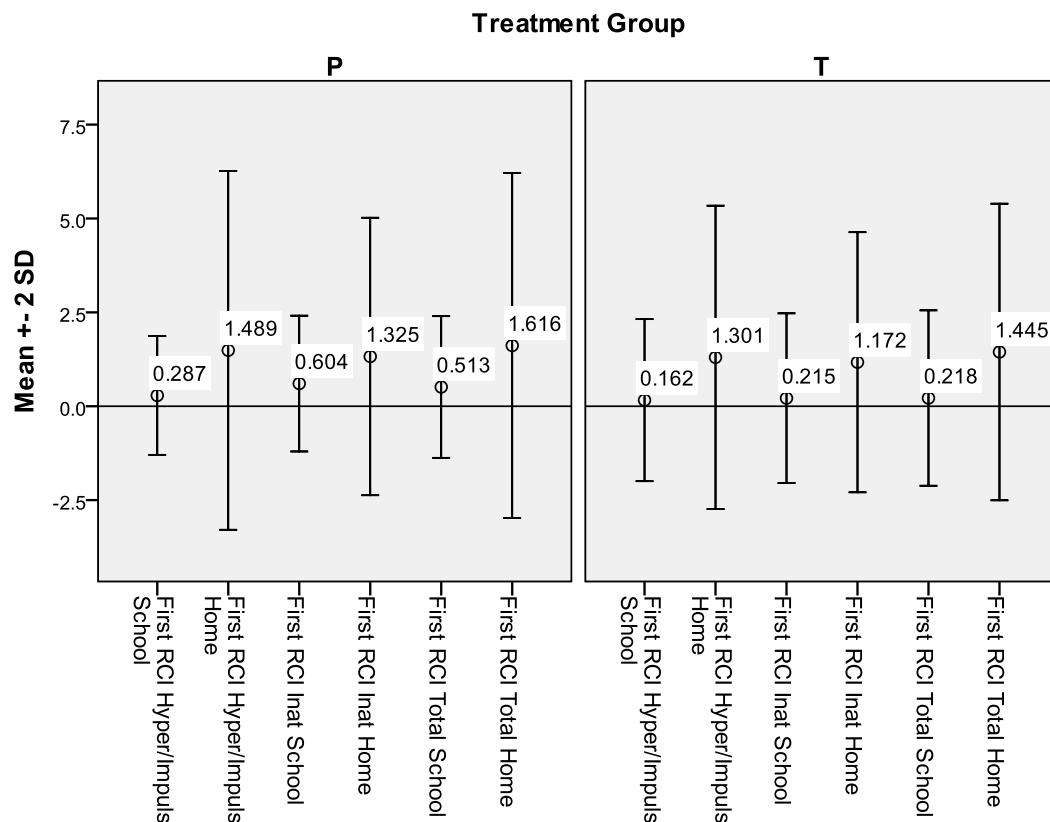
Jacobsen and Truax (1991) developed this method to facilitate the assessment of clinical significance. In this method the Reliable Change Index (RCI) was calculated by dividing the difference of the pre- and post-treatment scores by the standard error of difference (given by age and gender). A value of 1.96 or above signifies a clinically significant ( $p= 0.05$ ) reduction in symptoms, which is not attributable to measurement error.

The following tables and graphs show the RCI's for each of the assessment periods (i.e. between first and second assessments and between second and third assessments). The mean values as well as standard deviations and variances were also calculated.

Table 4.6 Table showing mean RCI's, standard deviations and RCI variances for first assessment period

	Mean	Maximum	Minimum	Standard Deviation	Variance
<b>RCI Hyper/Impulsivity (School)</b>	<b>.22</b>	<b>2.78</b>	<b>-2.28</b>	<b>.94</b>	<b>.89</b>
<b>RCI Hyper/Impulsivity (Home)</b>	<b>1.39</b>	<b>6.14</b>	<b>-2.04</b>	<b>2.16</b>	<b>4.68</b>
<b>RCI Inattention (School)</b>	<b>.40</b>	<b>2.26</b>	<b>-2.23</b>	<b>1.03</b>	<b>1.07</b>
<b>RCI Inattention (Home)</b>	<b>1.24</b>	<b>4.24</b>	<b>-2.03</b>	<b>1.76</b>	<b>3.09</b>
<b>RCI Total School</b>	<b>.36</b>	<b>2.45</b>	<b>-2.31</b>	<b>1.06</b>	<b>1.13</b>
<b>RCI Total Home</b>	<b>1.52</b>	<b>5.96</b>	<b>-2.24</b>	<b>2.09</b>	<b>4.39</b>

Figure 4.11 Graph showing mean RCI values (+/- 2 standard deviations) for first assessment period (panelled by treatment group)



From the above graph it is apparent that the variance in the RCI values is significant enough that there are no mean values that lie outside the standard deviation range of mean values of other components of the scale.

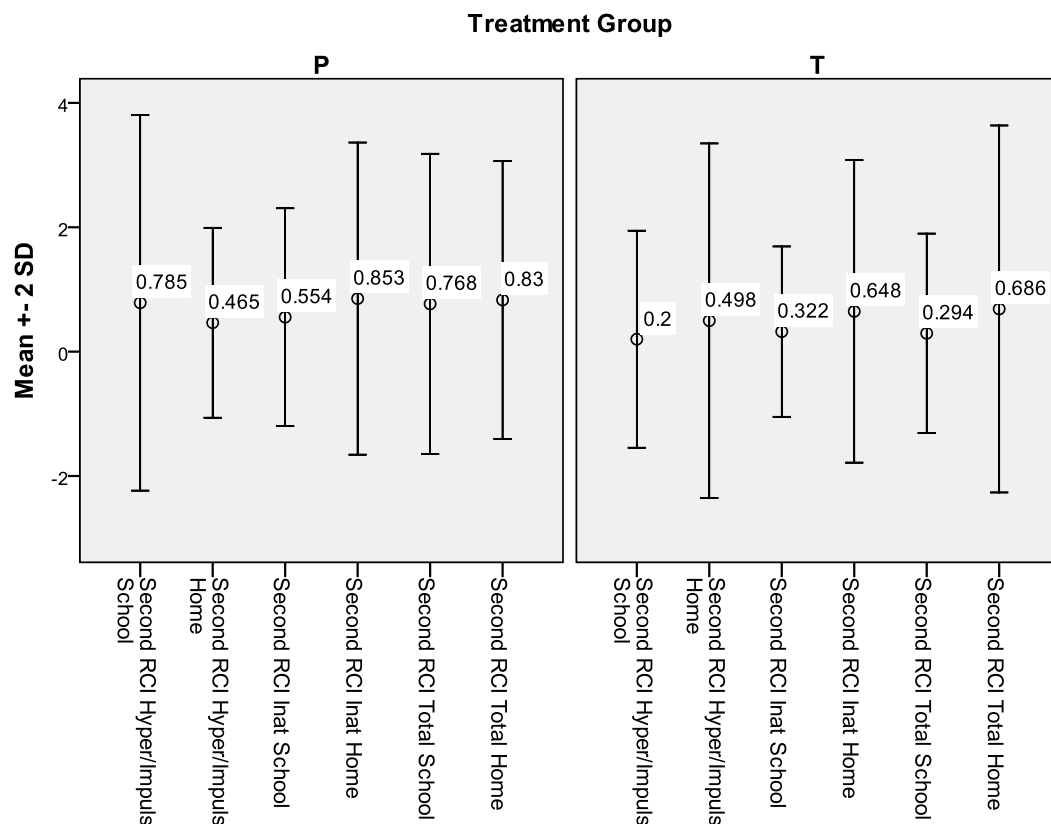
A second important observation is that the variance of the school derived RCI values is uniformly smaller than the variance of the home derived RCI values. This would indicate that the assessments conducted at school tend to deviate less from the mean. A possible explanation for this is that teachers are generally exposed to many more children than parents and so have a tendency to not attribute change so easily. When change is perceived it is perceived more uniformly. This supports the observation that the change in School Version scales seen in Figure 4.7 was uniformly less striking than the changes in Home Version scales. This is seen in the fact that the mean RCI

values for School Version scales (whether of Hyperactivity/Impulsivity or Inattention components) are uniformly lower than those of the Home Version scales.

Table 4.7 Table showing mean RCI's, standard deviations and RCI variances for second assessment period

	Mean	Maximum	Minimum	Standard Deviation	Variance
<b>RCI Hyperactivity/Impulsivity School</b>	<b>.47</b>	<b>3.64</b>	<b>-2.53</b>	<b>1.23</b>	<b>1.50</b>
<b>RCI Hyperactivity/Impulsivity Home</b>	<b>.48</b>	<b>4.33</b>	<b>-1.44</b>	<b>1.15</b>	<b>1.31</b>
<b>RCI Inattention School</b>	<b>.43</b>	<b>1.76</b>	<b>-1.00</b>	<b>.77</b>	<b>.60</b>
<b>RCI Inattention Home</b>	<b>.74</b>	<b>3.47</b>	<b>-1.13</b>	<b>1.22</b>	<b>1.48</b>
<b>RCI Total School</b>	<b>.52</b>	<b>3.06</b>	<b>-1.73</b>	<b>1.02</b>	<b>1.04</b>
<b>RCI Total Home</b>	<b>.75</b>	<b>4.28</b>	<b>-1.49</b>	<b>1.30</b>	<b>1.69</b>

Figure 4.12 Graph showing mean RCI values (+/- 2 standard deviations) for second assessment period (panelled by treatment group)



The table and graph describing the RCI values over the second assessment period support the comments made for the first assessment period. This strengthens the conclusions regarding the different assessment qualities of the Home and School Versions.

From both the above figures it is evident that there was apparent improvement in symptoms over both the treatment and placebo groups. The average RCI however was not strong enough to exclude the possibility of measurement error as the source of this change. ( $RCI \geq 1.96$ ). The large standard deviations also preclude any conclusion as to the statistical significance of the observed apparent change.



#### **4.5.2.2. NON-PARAMETRIC ASSESSMENT OF SIGNIFICANCE**

The Mann-Whitney test (a non-parametric, two independent samples test) was used to determine if there were any statistically significant differences in RCI's between Treatment and Placebo Groups.

Each treatment period was assessed separately i.e. was there a significant difference in the Reliable Change Indices of the treatment group versus the placebo group between the initial and second assessment, and between the second and third assessment.

Further, the RCI's of both the Hyperactivity/Impulsivity and Inattention components were assessed as well as the RCI's of the Total scale result. These were conducted for both the Home and School Versions of the test.

##### **a) First treatment period (between first and second assessment)**

Null Hypothesis: There was no significant difference in the RCI's of any of the components when comparing treatment and placebo groups.

Alternative Hypothesis: There was a significant difference in one or some of the RCI's of the different components when comparing treatment and placebo groups

Table 4.8 below shows the results of the Mann-Whitney U test for the first assessment period. No significant results were obtained for any of the components. There were thus no instances in which the null hypothesis could be rejected. There was a reasonable chance that the observed differences in the two groups could have been attributable to random occurrence.

Table 4.8 Table showing the results of the Mann Whitney U test for the first assessment period

	Mann-Whitney U	Asymp. Sig. (2-tailed)	Exact Sig. [2*(1-tailed Sig.)]
<b>First RCI Hyperactivity/Impulsivity: School</b>	<b>106</b>	<b>0.801</b>	<b>0.822</b>
<b>First RCI Hyperactivity/Impulsivity: Home</b>	<b>108.5</b>	<b>0.884</b>	<b>0.886</b>
<b>First RCI Inattention: School</b>	<b>89.5</b>	<b>0.349</b>	<b>0.355</b>
<b>First RCI Inattention: Home</b>	<b>108.5</b>	<b>0.884</b>	<b>0.886</b>
<b>First RCI Total School</b>	<b>92.5</b>	<b>0.416</b>	<b>0.423</b>
<b>First RCI Total Home</b>	<b>107.5</b>	<b>0.852</b>	<b>0.854</b>

b) Second treatment period (between second and third assessment)

Null Hypothesis: There was no significant difference in the RCI's of any of the components when comparing treatment and placebo groups.

Alternative Hypothesis: There was a significant difference in one or some of the RCI's of the different components when comparing treatment and placebo groups

Table 4.9 below shows the results of the Mann-Whitney U test for the second assessment period. No significant results were obtained for any of the components. There were thus no instances in which the null hypothesis could

be rejected. There was a reasonable chance that the observed differences in the two groups could have been attributable to random occurrence.

Table 4.9 Table showing the results of the Mann Whitney U test for the second assessment period

	Mann-Whitney U	Asymp. Sig. (2-tailed)	Exact Sig. [2*(1-tailed Sig.)]
<b>Second RCI Hyperactivity/Impulsivity: School</b>	<b>94</b>	<b>0.451</b>	<b>0.473</b>
<b>Second RCI Hyperactivity/Impulsivity: Home</b>	<b>102.5</b>	<b>0.691</b>	<b>0.697</b>
<b>Second RCI Inattention: School</b>	<b>91</b>	<b>0.381</b>	<b>0.4</b>
<b>Second RCI Inattention: Home</b>	<b>106</b>	<b>0.803</b>	<b>0.822</b>
<b>Second RCI Total: School</b>	<b>77.5</b>	<b>0.151</b>	<b>0.154</b>
<b>Second RCI Total: Home</b>	<b>98.5</b>	<b>0.574</b>	<b>0.58</b>

c) Combined treatment period (between first and final/third assessment)

Null Hypothesis: There was no significant difference in the RCI's of any of the components when comparing treatment and placebo groups.

Alternative Hypothesis: There was a significant difference in one or some of the RCI's of the different components when comparing treatment and placebo groups.

Table 4.10 below shows the results of the Mann-Whitney U test for the combined assessment period. No significant results were obtained for any of the components. There were thus no instances in which the null hypothesis could be rejected. There was a reasonable chance that the observed differences in the two groups could have been attributable to random occurrence.

Table 4.10 Table showing the results of the Mann Whitney U test for the combined assessment period

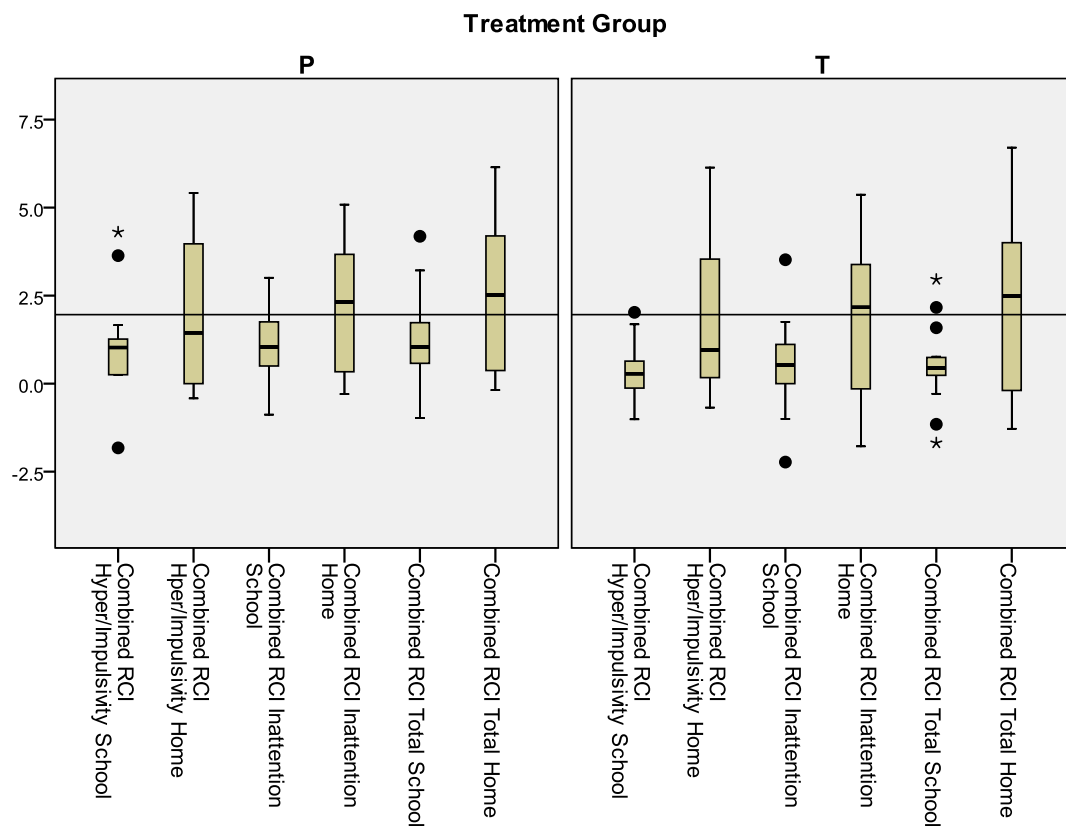
	Mann-Whitney U	Asymp. Sig. (2-tailed)	Exact Sig. [2*(1-tailed Sig.)]
<b>Combined RCI Hyperactivity/Impulsivity: School</b>	<b>73.500</b>	<b>.109</b>	<b>.110</b>
<b>Combined RCI Hyperactivity/Impulsivity: Home</b>	<b>109.500</b>	<b>.917</b>	<b>.918</b>
<b>Combined RCI Inattention: School</b>	<b>74.500</b>	<b>.118</b>	<b>.120</b>
<b>Combined RCI Inattention: Home</b>	<b>101.500</b>	<b>.662</b>	<b>.667</b>
<b>Combined RCI Total: School</b>	<b>66.000</b>	<b>.056</b>	<b>.058</b>
<b>Combined RCI Total: Home</b>	<b>100.500</b>	<b>.632</b>	<b>.637</b>

Figure 4.13 below graphically illustrates the spread of the combined RCI values between the treatment and placebo groups. The boxplot is a method of capturing 5 important descriptors of the data:

- Median value or 50<sup>th</sup> centile: this is represented by the heavy bar in the centre of the box.
- The 25<sup>th</sup> and 75<sup>th</sup> centiles (measures of the spread of data around the median): these are represented by the box boundaries (lower and upper).

- Minimum and maximum values are shown by the whiskers extending above and below the boxes.
- Statistical outliers are shown with a bullet ( • ) while extreme values are shown with a star (\*)

Figure 4.13 Boxplot showing the combined RCI values for both treatment and placebo groups



The horizontal line drawn through 1.96 is the line of clinical significance. Previous comments are supported in this plot namely:

- Assessments conducted at school show greater uniformity, less spread and less variation i.e. teachers appear either less perceptive of changes or more sceptical.
- Home assessments appear to be more impressive in both groups. This is offset however by greater spread.

- Both the placebo and treatment group show Total improvement above the line of clinical significance for the home score.

#### **4.5.3 RESULTS OF TREATMENT: WITHIN GROUPS**

While there was no statistically significant difference between treatment and placebo groups for the results, it was apparent that both groups experienced reduction in symptoms.

The significance of this reduction was assessed using the Wilcoxon Signed Rank test. i.e. was the reduction in the level of symptoms as assessed by the ADHD Rating scale IV large enough to make a chance/random reduction unlikely.

This was assessed for both placebo and treatment groups. For this assessment the raw scale scores were used rather than the RCI scores.

##### **a) Combined Group (placebo and treatment groups)**

Null hypothesis: There was no significant change in the level of symptoms for any of the components measured by the scale (for each of the treatment periods).

Alternative Hypothesis: There was a significant change in the level of symptoms for one or more than one of the components measured by the scale (for each of the treatment periods).

Table 4.11 Table showing results of Wilcoxon Signed Rank test for first treatment period: combined group

	Z	Asymp. Sig. (2-tailed)
Inattention Comp Home	-3.118 <sup>a</sup>	.002
Inattention Comp School	-2.185 <sup>a</sup>	.029
Hyperactivity/ImpulsivityComp Home	-3.002 <sup>a</sup>	.003
Hyperactivity/Impulsivity Comp School	-1.222 <sup>a</sup>	.222
Total Home	-3.292 <sup>a</sup>	.001
Total School	-2.077 <sup>a</sup>	.038

Table 4.12 Table showing results of Wilcoxon Signed Rank test for second treatment period: combined group

	Z	Asymp. Sig. (2-tailed)
Inattention Comp Home	-2.962 <sup>a</sup>	.003
Inattention Comp School	-2.662 <sup>a</sup>	.008
Hyperactivity/ImpulsivityComp Home	-2.040 <sup>a</sup>	.041
Hyperactivity/Impulsivity Comp School	-2.319 <sup>a</sup>	.020
Total Home	-2.817 <sup>a</sup>	.005
Total School	-2.598 <sup>a</sup>	.009

Table 4.13 Table showing results of Wilcoxon Signed Rank test for total treatment period: combined group

	Z	Asymp. Sig. (2-tailed)
Inattention Comp Home	-3.897 <sup>a</sup>	.000
Inattention Comp School	-3.195 <sup>a</sup>	.001
Hyperactivity/ImpulsivityComp Home	-3.830 <sup>a</sup>	.000
Hyperactivity/Impulsivity Comp School	-3.231 <sup>a</sup>	.001
Total Home	-3.930 <sup>a</sup>	.000
Total School	-3.490 <sup>a</sup>	.000

The above tables show that the subjects experienced significant levels of symptom reduction both across the trial and within each of the treatment periods. The null hypothesis was rejected for all components whether measured at home or school.

An exception to this was seen in the school assessment of Hyperactivity/Impulsivity in the first treatment period. The p-value was 0.222 so the null hypothesis was accepted.

#### b) Placebo and Treatment Groups analysed individually

Wilcoxon Signed Rank test was conducted for the treatment and placebo groups individually. All components were assessed across both treatment periods and the trial as a whole.



Null hypothesis: There was no significant change in the level of symptoms for any of the components measured by the scale (for each of the treatment periods).

Alternative Hypothesis: There was a significant change in the level of symptoms for one or more than one of the components measured by the scale (for each of the treatment periods).

Significant values were obtained. In the treatment group- most of the p-values were significant. The only exceptions were the individual assessments of the Hyperactivity/Impulsivity components as assessed at school. (Over the course of the trial, though, the subjects did show significant improvement).

Far fewer significant results were obtained within the placebo group. This indicates that although no statistically significant difference in results could be determined it appears that the treatment group responded better in terms of the magnitude and significance of their reduction in symptoms.

Table 4.14 Table showing results of Wilcoxon Signed Rank test for treatment group across different time periods. (Significant p-values values are in bold)

Group	Treatment period	Component	Z	Asymp. Sig (2-tailed)
Treatment	First	Inattention Comp School	-2.145 <sup>a</sup>	<b>.032</b>
		Inattention Comp Home	-2.275 <sup>a</sup>	<b>.023</b>
		Hyperactivity/Impulsivity School	-1.388 <sup>a</sup>	.165
		Hyperactivity/Impulsivity Home	-2.048 <sup>a</sup>	<b>.041</b>

		Total School	-1.964 <sup>a</sup>	<b>.050</b>
		Total Home	-2.237 <sup>a</sup>	<b>.025</b>
	Second	Inattention Comp School	-2.099 <sup>a</sup>	<b>.036</b>
		Inattention Comp Home	-2.237 <sup>a</sup>	<b>.025</b>
		Hyperactivity/Impulsivity School	-1.729 <sup>a</sup>	.084
		Hyperactivity/Impulsivity Home	-2.047 <sup>a</sup>	<b>.041</b>
		Total School	-2.100 <sup>a</sup>	<b>.036</b>
		Total Home	-2.267 <sup>a</sup>	<b>.023</b>
	Complete Trial	Inattention Comp School	-2.876 <sup>a</sup>	<b>.004</b>
		Inattention Comp Home	-3.046 <sup>a</sup>	<b>.002</b>
		Hyperactivity/Impulsivity School	-2.652 <sup>a</sup>	<b>.008</b>
		Hyperactivity/Impulsivity Home	-2.728 <sup>a</sup>	<b>.006</b>
		Total School	-3.048 <sup>a</sup>	<b>.002</b>
		Total Home	-2.983 <sup>b</sup>	<b>.003</b>

Table 4.15 Table showing results of Wilcoxon Signed Rank test for placebo group across different time periods. (Significant p-values values are in bold)

Placebo	First	Inattention Comp School	-1.009 <sup>a</sup>	.313
		Inattention Comp Home	-2.304 <sup>a</sup>	<b>.021</b>
		Hyperactivity/Impulsivity School	-.446 <sup>a</sup>	.656
		Hyperactivity/Impulsivity Home	-2.398 <sup>a</sup>	<b>.017</b>
		Total School	-1.158 <sup>a</sup>	.247
		Total Home	-2.406 <sup>a</sup>	<b>.016</b>
	Second	Inattention Comp School	-1.729 <sup>a</sup>	.084
		Inattention Comp Home	-1.957 <sup>a</sup>	<b>.050</b>
		Hyperactivity/Impulsivity School	-1.747 <sup>a</sup>	.081
		Hyperactivity/Impulsivity Home	-1.313 <sup>a</sup>	.189
		Total School	-1.762 <sup>a</sup>	.078
		Total Home	-1.856 <sup>a</sup>	.063
	Complete Trial	Inattention Comp School	-1.616 <sup>a</sup>	.106
		Inattention Comp Home	-2.556 <sup>a</sup>	<b>.011</b>
		Hyperactivity/Impulsivity School	-1.718 <sup>a</sup>	.086
		Hyperactivity/Impulsivity Home	-2.710 <sup>a</sup>	<b>.007</b>
		Total School	-2.021 <sup>a</sup>	<b>.043</b>
		Total Home	-2.536 <sup>b</sup>	<b>.011</b>

#### **4.5.4 CORRELATION ASSESSMENT: POTENCY CHOICE**

The data was analysed according to the potency choice in the treatment protocol. Due to the wide variety of treatment protocols and potency selections the analysis was performed by combining certain of the potency choices into one category.

The combination was as follows:

- Potency 1: 30CH plussed
- Potency 2: Other choices (30CH, 200CH, M, LM1, or combinations thereof)

Analysis was performed using the Mann-Whitney U test for 2 independent samples. The RCI's were assessed for significant difference between those subjects given 30CH plussed remedies and those given other dosage forms.

Null hypothesis: There was no significant difference in the RCI's for subjects given different potency forms.

Alternative Hypothesis: There was a significant difference in the RCI's for subjects given different dosage forms,

The significance level was set at 5%. ( $p=0.05$ )

a) First treatment period

Table 4.16 below shows the values of the Mann-Whitney U tests for the RCI's of the first treatment period (i.e. between the first and second assessment using the ADHD Rating Scale IV). Significant results were obtained i.e.

$p \leq 0.05$  and the null hypothesis was rejected. Dosage form had a statistically significant effect on RCI's for the first treatment period.

Table 4.16 Table showing results of the Mann-Whitney U test on RCI's for first treatment period

	Mann-Whitney U	Asymp. Sig. (2-tailed)	Exact Sig. [2*(1-tailed Sig.)]
First RCI Hyperactivity/ImpulsivitySchool	56.000	.021	.022
First RCI Hyperactivity/ImpulsivityHome	91.000	.414	.432
First RCI Inat School	34.000	.001	.001
First RCI Inat Home	45.500	.006	.005
First RCI Total School	37.000	.002	.001
First RCI Total Home	57.000	.025	.025

The results were significant for all components barring the Home Assessment of the Hyperactivity/Impulsivity component.

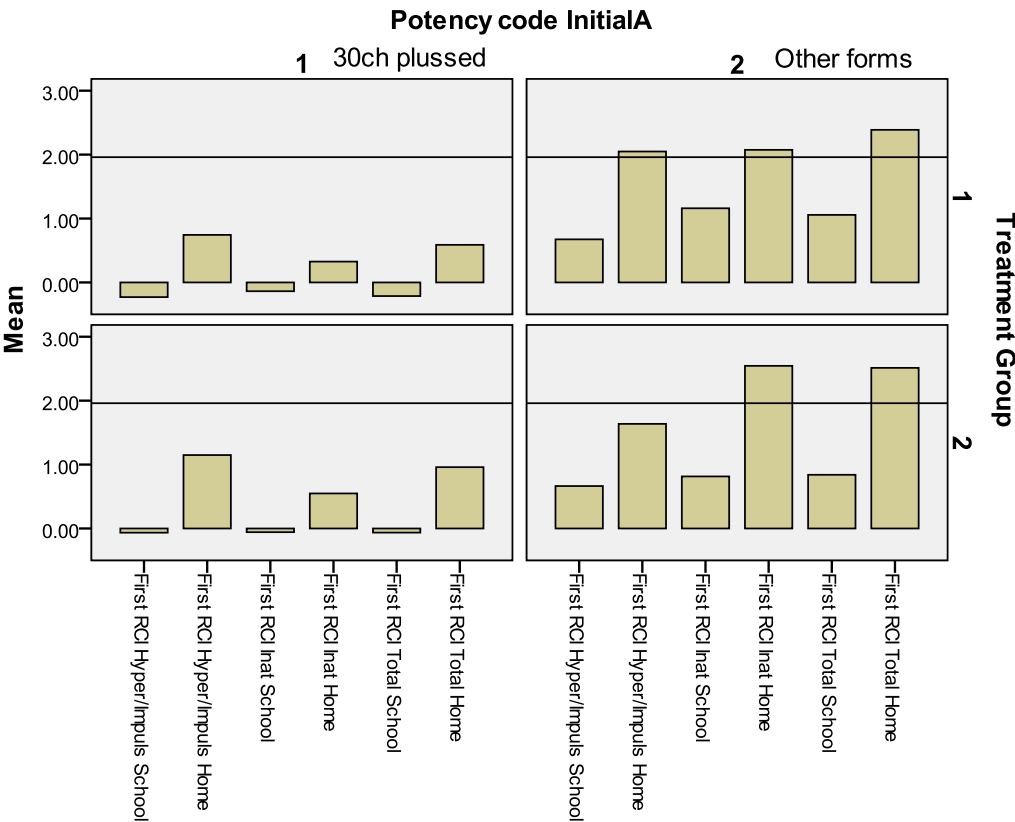
The same test was conducted (i.e. Mann Whitney U test) excluding all placebo cases. This had the effect of removing the significance i.e. there was no difference to the RCI's due to dosage form in the treatment group. In other words, by excepting the placebo group, it was apparent that the dosage form in which remedies were given had no statistically significant impact on the measured changes.

Table 4.17 Table showing results for the Mann-Whitney U test on RCI's of the treatment group for first treatment period

	Mann-Whitney U	Asymp. Sig. (2-tailed)	Exact Sig. [2*(1-tailed Sig.)]
First RCI Hyperactivity/ImpulsivitySchool	9.000	.069	.083 <sup>a</sup>
First RCI Hyperactivity/ImpulsivityHome	17.000	.461	.518 <sup>a</sup>
First RCI Inat School	12.500	.181	.190 <sup>a</sup>
First RCI Inat Home	10.000	.096	.112 <sup>a</sup>
First RCI Total School	9.000	.071	.083 <sup>a</sup>
First RCI Total Home	14.000	.257	.298 <sup>a</sup>

Figure 4.14 graphically depicts the differences between the two groups

Figure 4.14 Graph showing mean RCI's for treatment and placebo groups (panelled by dosage form) for first treatment period



From the graph above, it appears that the 30CH plussed form initiated less response in terms of measured changes. As a whole this is true (significant p-values for Mann-Whitney test above) however considering treatment group alone removes the statistical significance of this difference (i.e. it is possible that in a sample of this size, such an effect could have been due to chance).

b) Second treatment period

Table 4.18 below shows that values of the Mann- Whitney U tests for the RCI's of the second treatment period (i.e. between the second and third

assessment using the ADHD Rating Scale IV). No Significant results were obtained i.e.  $p > 0.05$  and the null hypothesis was not rejected. Dosage form had no statistically significant effect on RCI's for the second treatment period.

Table 4.18 Table showing results of the Mann-Whitney U test on RCI's for second treatment period

	Mann-Whitney U	Asymp. Sig. (2-tailed)	Exact Sig. [2*(1-tailed Sig.)]
Second RCI Hyperactivity/ImpulsivitySchool	<b>98.500</b>	<b>.572</b>	.580 <sup>a</sup>
Second RCI Hyperactivity/ImpulsivityHome	<b>110.000</b>	<b>.933</b>	.951 <sup>a</sup>
Second RCI Inat School	<b>101.000</b>	<b>.646</b>	.667 <sup>a</sup>
Second RCI Inat Home	<b>111.000</b>	<b>.967</b>	.984 <sup>a</sup>
Second RCI Total School	<b>111.500</b>	<b>.983</b>	.984 <sup>a</sup>
Second RCI Total Home	108.000	.868	.886 <sup>a</sup>

Removing the placebo group from the consideration had no effect on the statistical impact of dosage form. i.e. there was no significant impact of dosage form on the observed RCI's for the second treatment period in the treatment group.

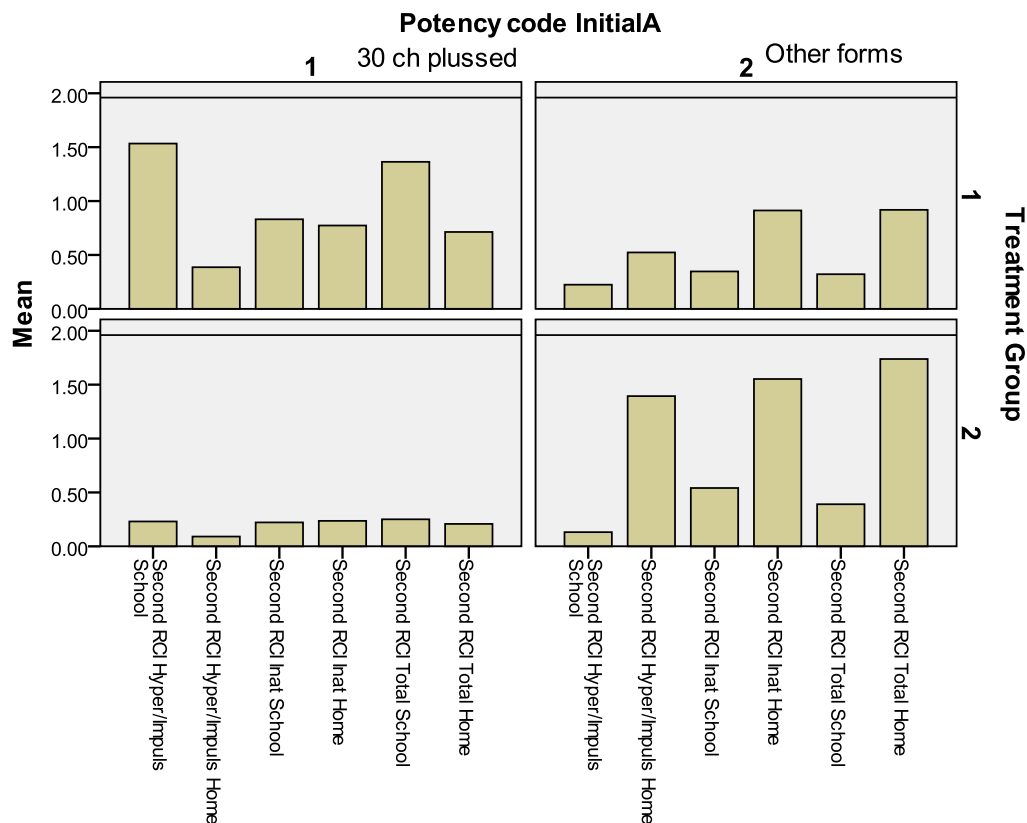


Table 4.19 Table showing results for the Mann-Whitney U test on RCI's of the treatment group for second treatment period

	Mann-Whitney U	Asymp. Sig. (2-tailed)	Exact Sig. [2*(1-tailed Sig.)]
Second RCI Hyperactivity/ImpulsivitySchool	21.000	.841	.898 <sup>a</sup>
Second RCI Hyperactivity/ImpulsivityHome	18.500	.592	.606 <sup>a</sup>
Second RCI Inat School	17.000	.460	.518 <sup>a</sup>
Second RCI Inat Home	18.500	.592	.606 <sup>a</sup>
Second RCI Total School	21.000	.841	.898 <sup>a</sup>
Second RCI Total Home	16.500	.423	.438 <sup>a</sup>

Figure 4.15 graphically depicts the differences between the two groups

Figure 4.15 Graph showing mean RCI's for treatment and placebo groups (panelled by dosage form) for second treatment period



#### 4.5.5 CORRELATION ASSESSMENT: ETHNIC GROUPING

The data was analysed according to the ethnic group of the sample. The ethnic grouping used was as follows:

- Caucasian: Group 1
- Asian: Group 2
- African: Group 3

Analysis was performed using the Kruskal-Wallis test for independent samples. The RCI's were assessed for significant difference between ethnic groupings.

Null hypothesis: There was no significant difference in the RCI's for subjects from different ethnic groups.

Alternative Hypothesis: There was a significant difference in the RCI's for subjects from different ethnic groups.

The significance level was set at 5%. ( $p=0.05$ )

As seen in table 4.20 below, the results were mostly not statistically significant. The null hypothesis was thus accepted: there was no difference in RCI's due to ethnic group. The test was performed for both treatment periods across all components (i.e. both Home and School Versions of Inattention and Hyperactivity/Impulsivity).

The only component in which ethnic group appeared to have a statistically significant result was in the Home Version assessment of Inattention component for the second treatment period. In light of the other non-significant values it is safe to assume that this is artefactual or due to chance. A test for significance returns the probability that any observed relationship is due to chance. If the probability is low (less than 5% usually) then this is said to be significant. However there is still a chance that the relationship was chance. In this case where all other components were not significant, it is safe to assume that this apparent relationship i.e. ethnic group to home assessment of Inattention component in the second treatment period was chance.

Table 4.20 Table showing results for the Kruskal-Wallis H test for ethnic grouping

Treatment Period and Component	Chi-Square	Df	Asymp. Sig. (P-value)
First Treatment Period: Hyperactivity/ImpulsivitySchool	1.735	2	.420
First Treatment Period: Hyperactivity/ImpulsivityHome	4.841	2	.089
First Treatment Period: Inattention School	1.576	2	.455
First Treatment Period: Inattention Home	4.843	2	.089
First Treatment Period: Total School	1.499	2	.473
First Treatment Period: Total Home	5.023	2	.081
Second Treatment Period: Hyperactivity/ImpulsivitySchool	1.665	2	.435
Second Treatment Period: Hyperactivity/ImpulsivityHome	2.288	2	.319
Second Treatment Period: Inattention School	2.125	2	.346
Second Treatment Period: Inattention Home	6.733	2	.035
Second Treatment Period: Total School	2.068	2	.356
Second Treatment Period: Total Home	5.694	2	.058

## CHAPTER 5: DISCUSSION

### 5.1 DEMOGRAPHICS

Participants were recruited by means of convenience sampling thus discrimination in terms of age, gender and race was not present. Participants did, however have to be fluent in English, due to language limitations of the researcher and the rating scales. This could have influenced race demographics, explaining the poor representation of African participants (3%) and the high Asian (57%) and Caucasian (40%) representation. As far as the study results are concerned, it was discerned, using Kruskal-Wallis test (Table 4.20) for independent samples, that there was no significant difference in the Reliable Change Index (RCI), calculated to facilitate the assessment of clinical significance, for subjects from different ethnic groups.

The gender demographics (Table 4.1 and Figure 4.1) confirm the fact that AD/HD has a significantly higher prevalence amongst boys than girls. Almost 87% of the participants in this study were boys. Most AD/HD studies (Bilici *et al.*, 2003; Frei & Thurneysen, 2001) reflect this male predominance. It is in question as to whether or not boys' symptoms are by nature more notable and have a higher impact than girls' symptoms, as boys are more prone to aggressive and antisocial behaviour (Davison & Neale, 2001), and the fact that the predominantly inattentive type is found more commonly in girls, suggesting that female AD/HD is marked more by inattention. It could also be a case that girls suffering with AD/HD are under-diagnosed due to a lack of knowledge about hyperactive behaviour in females (Dray, Campbell & Gilmore, 2006).

There are no statistics as to which types of AD/HD were most dominant in the study as it was found that children were mostly diagnosed with the broad term of AD/HD. It was also not necessary for this study to determine the type as the treatment was based on the individual symptoms that the participant

exhibited and not on the diagnosis. This individualised approach is demonstrated by the variety of remedies utilised in this study (Chapter 4, Table 4.3). Allopathic drug treatment is also not prescribed according to the type of AD/HD. This could be a reason why diagnosticians do not always further classify the presenting AD/HD.

## **5.2 ADHD RATING SCALE-IV: HOME AND SCHOOL VERSIONS**

In this study both the ADHD Rating Scale-IV Home and School Versions (Appendices B and C) were used to determine change. Detailed analysis could be conducted as each rating scale was broken down into 3 components, namely Inattention, Hyperactivity/Impulsivity and Total.

From Figures 4.5, 4.6 and 4.7, it is clear that improvements reflected by the Home Versions were more significant across all 3 components in comparison to the School Versions. It is noted that the School Versions showed less variance but also less change whereas the Home Versions showed more change but more variance. This is clearly demonstrated by Figures 4.11 and 4.12. Correlation testing using scatterplots (Figures 4.8, 4.9 & 4.10), demonstrated no apparent correlation between the 2 versions of the rating scales at any of the assessments, further evidence that the assessments across the 2 settings seem to be quite different. However, statistical analysis using Wilcoxon Signed Rank Test, comparing the sub-components of the Home and School Versions, revealed no significant difference in using either version of the scale and it was concluded that the observed differences had a high enough probability of being attributed to chance or differences in the variance of the two groups.

The scale is reliant on the views and opinions of the person completing it and thus it become a fairly subjective representation of the child's behaviour. When it comes to rating a child's behaviour, or even whether a child has a problem at all, parent-teacher disagreement is quite common (Barkley, 2005 pg 159). The greater improvement seen in the Home Version Scale in the

study could be explained by a possible expectation of improvement demonstrated by the parents who made the effort to join the study and come in for consultations, compared to the teachers who would, in most cases, have less expectation of improvement as they were less involved. This could be seen as a therapeutic effect of the study, case-taking and consultation. Another factor could be that the Home Version was completed near the end of each consultation, perhaps resulting in the researcher inadvertently influencing the parent's objectivity of the child's improvements as the consultation involved questioning to identify even the most subtle changes in the child. These aforementioned reasons for the greater improvement seen in the Home Versions could also be used to explain the greater variance. It was noticed during the study that parents and guardians were generally quite emotive about their child's condition and were far more sensitive to any changes seen in the child. This alone could explain the greater change and variance seen in the Home vs School results. As mentioned in Chapter 4, teachers are also exposed to many more children than parents are, and thus tend to not attribute change as easily in the individual. This is supported by the fact that the mean Reliable Change Index (RCI) values (Tables 4.6-4.10 and Figures 4.11-4.13) for the School Versions were uniformly lower than the Home Version values, and less variance was demonstrated.

Incorporating qualitative data would ensure a more rounded evaluation of the outcome of the study.

### **5.3 RESULTS OF TREATMENT VS PLACEBO GROUP**

The initial graphical analysis (Figures 4.5, 4.6 and 4.7) of the results from the ADHD Rating Scale-IV demonstrated sizeable improvements in both the placebo and treatment group across all 3 components of the scales and in both versions of the scale. On correlation assessment the Reliable Change Index (RCI) was calculated to facilitate the assessment of clinical significance. The RCI was calculated by dividing the difference of the pre- and post-treatment scores by the standard error of difference (given by age and

gender). A value of 1.96 or above signified a clinically significant ( $p=0.05$ ) reduction in symptoms, which is not attributed to observer error. Tables 4.6 and 4.7, and Figures 4.11 and 4.12 show that there was apparent improvement in symptoms in both groups across both assessment periods but the average RCI was not strong enough to exclude the possibility of observer error as the source of this change ( $RCI \geq 1.96$ ). Thus there was no statistically significant improvement in either group.

The Mann–Whitney test (a non-parametric, two independent sample test) was conducted to determine whether there was enough of a difference in changes between the 2 groups to conclude that the effect was due to treatment or placebo. No significant results (Table 4.8, 4.9 and 4.10) were obtained for any of the components thus the null hypothesis that there was no significant difference in the RCI's of any of the components when comparing treatment and placebo groups could not be rejected. There was a reasonable chance that the observed differences could have been attributed to random occurrence.

While there was no statistically significant difference between treatment and placebo groups for the results, it was apparent that both groups experienced reductions in symptoms.

Wilcoxon signed rank test was applied, using the raw scale scores, to determine the significance of the reduction. The combined placebo and treatment group showed significant levels of symptom reduction both across the trial and within each of the treatment periods (Table 4.11, 4.12 and 4.13). Intra-group comparison (within the treatment group and placebo group, individually) using Wilcoxon signed rank test revealed significant change in the level of symptoms in both groups. In the treatment group (Table 4.14), most of the p-values were significant ( $p \leq 0.05$ ), demonstrating improvement in symptoms, with the exception of the individual assessments of the Hyperactivity/Impulsivity components as assessed at school. The results



obtained for the placebo group were far less significant (Table 4.15). According to Table 4.15 and 4.16, across the first assessment period, the treatment group demonstrated significant ( $p \leq 0.05$ ) p-values in 5 of the 6 components, whilst the placebo group only demonstrated significant values in 3 of the 6 components. In the second assessment period, the treatment group again demonstrated significant p-values in 5 of the 6 components, whilst the placebo group showed significant values in only 1 component. Across the complete trial, the treatment group showed significant values over all the components, with the placebo group showing significant improvement in only 4 of the 6 components. These observations indicate that on the whole, although no statistically significant differences in results between the 2 groups could be determined, it appears that the treatment group responded better in terms of magnitude and significance of their reduction in symptoms.

Parents/guardians and teachers' expected treatment outcomes may have influenced their perception of the degree of improvement of symptoms. This could be explained by the fact that most of the participants in the trial had a history of taking allopathic drugs such for AD/HD symptoms. The participants still on such treatment chose to stop their treatment 1 week before the study, as per study inclusion/exclusion criteria, for various reasons (e.g. side-effects and seeking alternative treatment). Parents/guardians and teachers treatment expectations were thus based on their previous allopathic treatments and the speed with which they alleviated AD/HD symptoms. These expectations were of a notable decrease in hyperactivity, impulsivity, difficult behaviour, aggression, and an improvement in concentration in a relatively short duration. These expectations and the need for fast amelioration of symptoms place pressure on the treatment process and are in conflict with the usual slow amelioration induced by homoeopathic treatment (Frei *et al.*, 2007). From previous homoeopathic studies of longer duration (e.g. Frei *et al.*, 2007), it is apparent that it takes a considerable period of time to demonstrate improvements in AD/HD symptoms.

## **5.4 PLACEBO**

The term “placebo” derives from the Latin “I shall please” (Diederich & Goetz, 2008 pg 677). The conventional definition of placebo is that it is a tool that allows for objective and unbiased evaluation of a therapy in the context of a randomised control trial, as it is considered physiologically inactive. Double-blind, placebo-controlled procedure is seen as the only way to definitively find out the contribution and impact of the proposed treatment on the condition (Kupers & Marchand, 2005). This is said to ensure the validity of the study in making sure the treatment is effective and not just the parents or researcher imagining improvements in the children’s behaviour. In this study the researcher, clinicians, parents and participants were blind as to which participants were given placebo to rule out the possibility of inadvertently influencing the results. This was to give the results of the study further credibility.

When dealing with placebo-controlled studies one has to take into consideration the placebo effect. On statistical comparison between placebo and treatment, placebo treatment outcomes may in fact mask, diminish, or increase the calculated treatment effect (Diederich & Goetz, 2008 pg 681). Many improvements seen in clinical trials are a result of positive patient expectations. The placebo effect is believed to be a psychobiological response. Treatment induces mental anticipation of clinical improvement and this anticipation may be strong enough to induce neurochemical alterations in the brain. A positive placebo response is seen in up to 50% of patients with Parkinson’s disease, pain syndromes, and depression (Diederich & Goetz, 2008 pg 677). Diederich and Goetz (2008) go further to note that greater placebo responses were documented in studies that had 50% placebo assignment likelihood to those with lower placebo assignment likelihood, bringing in the role of expectation. The placebo effect appears to be directly related to the level of uncertainty. This could be due to the fact that patients are aware that they may be on placebo and are thus more sensitised to any changes experienced and may be trying to determine for themselves whether they are on treatment or not. They will thus be primed and sensitised to the

study, increasing the mental anticipation of improvement, making them more likely to show positive results.

Placebo treatment may be one of the most effective medicines and is seen by some as the perfect medicine. The placebo effect may be regarded as a valid aspect of any therapeutic encounter and positive patient interaction. When one considers placebo in this light it may be seen as a valid treatment, making the results admissible for consideration (Steele, 2008). It still does not bring us closer to the objective of this study (i.e. to determine the efficacy of homoeopathic simillimum in the treatment of AD/HD) but does aid us in accepting that making direct comparisons with placebo is not quite so simple or conclusive. Taking these views into consideration makes the statistical insignificance of the results of this study a little less insignificant.

## **5.5 SIMILLIMUM TREATMENT**

Table 4.3 and Figure 4.3 demonstrate the breakdown of remedies prescribed during the course of the study. The 3 most commonly prescribed remedies were *Calcarea carbonica*, *Sulphur* and *Phosphorus*. These are all commonly used polychrests. There is debate as to the prevalent prescribing of polychrests. They are better known and studied by homoeopaths, and more extensively documented and well-represented in repertories. One has to question whether the prescriber missed the more obscure, under-represented remedies over the possibly over-represented polychrests, hampering the prescribing of the true simillimum.

An important aspect that must be considered in placebo-controlled studies with homoeopathic simillimum is that it often takes time to find the simillimum. It is never a surety when prescribing that the prescriber finds the optimal remedy at the first consultation. This is often the case even with experienced homoeopaths. Even when dealing with such homoeopaths, gender, age, approach, case-taking skills and life-experience all inadvertently influence the case and the prescription. When you compound this with the limited

experience of the researcher, aided by clinicians who relied only on information relayed to them by the researcher, the margin for error in reaching the simillimum becomes even wider. In this study there were only 2 opportunities to find the simillimum and in some cases it is still not felt that the true simillimum was found. It is also important to consider the limited duration of the study with regards to finding the correct remedy. In practice one may have persisted with a remedy for longer before changing it but in the trial there were only 2 opportunities to prescribe so the change of prescription and the decision that not enough change had been observed was made fairly hastily. This emphasises the importance of a longer duration study.

In the two-phased randomised controlled trial with simillimum treatment in hyperactivity by Frei *et al.* (2007) participants had to reach a pre-defined level of improvement before being eligible for phase 2. Participants only reached eligibility for the second phase (double-blind placebo-controlled phase) after a median time of 5 months (range 1-18 months), and with a median of 3 different medications (range 1-9 medications). Of the participants in phase 1, 13% never reached eligibility for phase 2. When these statistics are considered one realises how idealistic we may be in the expectation of significant results in the current study. It was noted that parents often found it difficult to describe the symptoms of their child, leading to changeability, and thus the initial phase of treatment was characterised by the use of different medications until the optimal remedy was found. Frei *et al.* (2007) conclude that due to the necessity of finding the optimal remedy (simillimum) before response to treatment can be expected, randomisation at the start of a study of this nature has a high risk of failure to demonstrate a specific treatment effect if the observation time is shorter than 12 months. The current study was randomised from the start, conducted over only 2 months and there were only 2 opportunities to find the correct simillimum.

In essence, a treatment that one cannot be sure is even being administered, is being compared to placebo, which explains the similarity in results in the 2 groups.

## **5.6 POTENCY**

Table 4.4 and Figure 4.4 demonstrate the potency breakdown. The most commonly prescribed potency was 30CH plussed. The next most prevalent was LM1, demonstrating the favouring of liquid potency form by the researcher. The choice of potency was based on Hahnemann's three-part guideline for potency selection: an observation of the nature of disease, the nature of the patient, and the nature of the remedy (De Schepper, 2006 pg 56). The researcher generally felt that, given the chronic nature of the condition and how it is conventionally treated, a daily dose was a viable treatment option. Many of the participants had previous allopathic treatment thus there was a high expectation by the parents/guardians and participant of a daily dose. Daily dosing also acts as a regular reinforcement of the remedy, suited to the chronic nature of the condition and reduces the chance of the remedy being antidoted. The gentle nature of the 30CH plussed and LM potencies were well suited to the nature of the condition, the nature of the remedy (in the cases where these potencies was selected), and to treating children.

LM potencies were used due to the fact that they are one of the gentlest and most powerful of potencies (De Schepper, 2006 pg 56) and can be repeated on a daily basis.

The prevalence of using 30CH plussed potency was a personal preference made by the researcher. It is a desirable potency choice when frequent repetition of a remedy is required (Vithoulkas, 2004 pg 263). Low potencies are gentle and any aggravation is usually milder than with the higher potencies (De Schepper, 2006). Hahnemann comments in the 5<sup>th</sup> edition of Organon about the benefits of administering remedies in water, and of the

repetition of the remedy in shorter intervals to speed up healing (De Schepper, 2006 pg 62). The researcher feels that the 30CH plussed potency encompasses Hahnemann's highest ideal of cure, as stated in Aphorism 2 of the Organon (O'Reilly, 2001 pg 60):

*"The highest ideal of cure is the rapid, gentle and permanent restoration of health...in the shortest, most reliable, and least disadvantageous way..."*

The researcher did at times feel limited by the study design as she felt that a weekly powder could be a more viable treatment option for certain cases. This was due to patient compliance, and cases where there was a significant improvement in a short period of time and only a maintenance dose was required. It was noted by some of the parents/guardians of participants who received both drops and powders that the powders had a better response than the drops. Reducing dosage options could reduce variables in further studies of this nature.

On correlation assessment of potency choice, 30CH plussed alone was compared to all other dosage options (30CH, 200CH, M, LM1, or combinations thereof) to determine whether dosage form had an effect on the results. The Mann-Whitney U Test for 2 independent samples was performed and the RCI's were assessed for significant differences between the 2 groups (30CH plussed and other choices). The test was performed for both treatment periods. From Table 4.16 and Figure 4.14, it appeared that the 30CH plussed form initiated less response than other forms in the first treatment period. However, given the small sample size and the fact that considering the treatment group alone (Table 4.17) removes any statistical significance of a difference, such an effect could be due to chance. In the second treatment period (Table 4.18 and Figure 4.15), no significant results were obtained and it can be concluded that dosage had no statistically significant effect on RCI's.

It still remains an uncertainty to the researcher as to the best possible dosage form for the treatment of AD/HD. There are no set rules when it comes to choice of potency, and experience and observation play a large role (Vithoulkas, 2004 pg 213). Just as homoeopathy is about individualised treatment and finding the individual remedy, so should it also be about potency for the individual, rather than the group. The results on the statistical analysis of potency choice are also slightly under-representing the 30CH plussed dosage form as many of the combination treatments, represented in the 'Other forms' group were combinations of 30CH plussed and other potencies (e.g. 30CH plussed and M powders). It must ultimately be decided based on the individual sensitivities and susceptibility of the patient.

## **5.7 OBSTACLES TO CURE**

An incorrect prescription is not always due to the homoeopath's mistake. The patient could be withholding information for various reasons (e.g. abuse, shame, comfort) (De Schepper, 2006 pg 266), or parents could be finding difficulty describing their child's symptoms, leading to changeability, as discussed in 5.5, preventing the discovery of a clear symptom picture and the simillimum. In such cases it may take time to gain the trust of the patient and clarify symptoms before you are shown the true symptom picture.

Some of the cases could also have been confused due to the previous use of allopathic medicines for the treatment of the child's AD/HD symptoms. The 1-week delay in entering the trial after ceasing allopathic treatment is, in hindsight, too short a period to ensure a clear symptom picture.

The patient may have failed to take the remedy correctly, or the patient's lifestyle or changes therein could influence and obstruct the treatment (De Schepper, 2006 pg 273). Although participants were instructed not to change their lifestyle or diet, these are factors that naturally adjust over a 2-month period, especially as the parents/guardians, and in some cases even the participants, became more educated and aware of their body's needs (e.g.

some participants limited their intake of junk food, increased exercise and decreased television viewing).

There are also obstacles to cure to homoeopathic treatment that come with modern times, such as chlorination and fluoridation of our water, the drugs and chemicals in our food, air pollution, multiple vaccinations, the increasing use of X-rays, and overuse of drugs such as antibiotics, and strong suppressive treatments (De Schepper, 2006 pg 279), such as the allopathic drugs used to treat AD/HD.

Other obstacles to cure noted by the researcher were the prevalence of family problems amongst the participants. These included single parent families, divorced parents, and conflict within the family. On the other hand, there were situations where it was felt that the parents/guardians perhaps had expectations that were too high for the child's capabilities, or parents who were in-fact being over-zealous about their child's education and development. Thus it is felt that treatment of the whole family would lead to a more positive treatment outcome (De Schepper, 2006 pg 7), as it seems that some of the obstacles to cure lie within the family.

## **5.8 HOLISTIC IMPROVEMENT**

The ADHD Rating Scale-IV gives a very limited representation of improvement. Although the perspective of this study is the improvement in symptoms of inattention, hyperactivity and impulsivity, from a homoeopathic perspective, improvement on all levels is the higher objective. In the homoeopathic approach, and even more so in simillimum treatment, the case-taking, analysis, prescription and posology take into account the whole organism (De Schepper, 2006 pg 5,6).

Vithoulkas (2004) describes in *The Science of Homeopathy* that the 3 levels of the organism are physical, emotional and mental and that advancement of



pathology may be seen to move from the physical level to the emotional, then finally to the mental. The main symptom of AD/HD can be seen as inattention and this sits on the mental level. It is thus logical to assume that improvement in such cases would begin first on the mental level, and then move to the emotional level, and finally the physical level. This is according to Hering's Law of Cure that states: '*cure proceeds from above downward, from within outward, from the most important organs to the least important organs, and in the reverse order of appearance of symptoms*' (Vithoulkas, 2004 pg 231). Although the results of the study did not show statistically significant improvements in the AD/HD symptoms, this was only measured according to the rating scales. Parents/guardians and teachers made numerous comments to the researcher regarding improvements that they had noted in the child's AD/HD symptoms. This could indicate that the right simillimum has been prescribed but more time was needed to exert a change on the desired level, or that the scales were not detailed enough to reflect these changes. On the whole, the researcher noted improvements in emotional symptoms. The most striking example was of a *Veratrum album* case (Appendix N: Case 11) in which the child had suicidal tendencies and serious aggression problems, which included incidents of threatening family members with knives. The improvement reported by the parents and participant, and noticed by the researcher were quite remarkable. The child was happier within himself and was interacting more positively with those around him. Some general feedback from parents during the course of the trial was a decrease in aggression, improved self-discipline and application, a feeling of being less bothered by their disorder, and improved relationships. It is also felt by the researcher that with longer treatment duration greater improvement of AD/HD symptoms would become more apparent once possible pathology on the emotional level was addressed. With regards to the physical level, it was noted that in some cases physical symptoms showed improvement at follow up consultations. One participant had severe constipation since infancy, which improved on the remedy in the absence of significant improvements in concentration. Some of the children who had decreased appetites had improvements in appetite (it is not conclusive as to whether this improvement in appetite was attributed to previous appetite suppression as a side-effect of

allopathic drug treatment, or as a beneficial effect of the treatment.). The physical changes in the absence of improvement on the mental level could indicate, according to Vithoulkas, that the wrong remedy had been prescribed as improvement should start at the mental level, move to the emotional, and then only to the physical, but the researcher did not find any cases wherein there was improvement on the physical level without an overall improvement in well-being. In this study an improvement on the mental level was mostly gauged by a perception in school performance, as this was the focus of most parents, participants and teachers. More subtle improvements on the mental level could very likely have been missed.

A more qualitative approach of assessing improvement (e.g. a Quality of Life Scale) would be useful but most of the changes would still not be statistically measurable. This is a challenge when conforming a homoeopathic trial into an allopathic mould.

## **5.9 TRUE PREVALENCE OF AD/HD**

During the course of the study it was felt by the researcher and the clinicians that many of the participants did not truly fulfil all criteria for the diagnosis of AD/HD (Appendix A). Many experts feel that AD/HD is over-diagnosed, largely because criteria are applied inaccurately (Beers, 2006 pg 2483). It is felt that in a number of cases behaviour and attention problems clearly stemmed from problems at home or school. In other cases AD/HD symptoms were barely demonstrated. It is felt that there is gross over-diagnosis of this condition and that it is being used as an umbrella term for various behavioural problems. It is all too often the case that a paediatrician or general practitioner makes a diagnosis and prescribes medication after obtaining only a brief case-history from the parent (Sonna, 2005 pg 14).

The over-diagnosis may also be seen as an indicator of the break-down of the family unit, so prevalent in society today. Problems prevalent in the participants' families included, divorce, absent parents and family conflict. A

number of the participants were from dual-income homes, where both parents were out at work all day, resulting in the child being in the care of school and aftercare teachers all day and not getting the attention that they need from their parents. Another aspect to consider is the school system. Classrooms are usually grossly over-crowded, preventing individualised attention and help. This also leads to teachers feeling over-whelmed and frustrated, with a lowered threshold for tolerating behavioural and learning problems. Many believe that the real problem is cultural and that life has become so stressful that most adults feel overwhelmed by normal children (Sonna, 2005 pg 7). An interesting avenue of thought as to whether the condition is overdiagnosed or an adaptive response to an over-stimulated society could shed more light on its prevalence (Reichenberg-Ullman & Ullman, 2000 pg 23) The over-diagnosis could thus be an indication of modern society and our culture of placing great emphasis on normalcy and academic achievement. Parents seem to have set expectations for their children and they are more often chastised for their weaknesses than given encouragement to focus on and develop their strengths. Parents, teachers and the health professionals who diagnose them seem to forget that children are individuals.

## **CHAPTER 6: CONCLUSIONS AND RECOMMENDATIONS**

### **CONCLUSIONS**

There have been a number of treatment modalities introduced for the management of AD/HD. Conventional treatment however, consists mostly of pharmacological intervention (Davison & Neale, 2001).

The Multimodal Treatment Study of Children with AD/HD was a 14-month randomised clinical trial on treatment strategies for the condition. It was conducted on 579 elementary school boys and girls with AD/HD. The results of the study indicated that long-term combination treatments and medication-management alone were superior to intensive behavioural treatment and routine community treatment. The advantage of combined treatment was that children could be treated with lower doses of medicine, compared with the medication-only group (NIMH, 2008 pg 11). Multimodal treatment should consist of medication, behavioural therapy, and educational accommodations (DuPaul & Weyandt, 2006). This study confirms that a more holistic approach is required when dealing with this condition and that the medication does work at placating the problem behaviour but it is more effective and less medication is required when treatment involves other modalities.

The major problem with the AD/HD medications is the incidence of side-effects. Common adverse effects associated with these medications include loss of appetite with subsequent loss of weight, headaches, nausea, abdominal pain, sleeplessness and depression (Picton, 2005). There is also a lack of long-term studies to determine the effects of continuous treatment. Thus remedial schools, psychotherapy, behavioural therapy, nutritional and dietary modifications, and modalities such as homoeopathy should be taken into consideration and implemented before embarking on the pharmacological route.

On analysis, the results (Tables 4.8, 4.9 and 4.10) showed no statistically significant effect of treatment (i.e. no difference between treatment and placebo group), but across the whole trial and within each group (particularly the treatment group) subjects had significant reductions in symptoms (i.e. the reductions in symptoms were large enough that there was less than 5% chance that they were random fluctuations/effects). This was seen in both the treatment and placebo groups, as indicated by Tables 4.11, 4.12 and 4.13, but more significant reductions were seen in the treatment group, indicated by Table 4.14. As discussed in Chapter 5, this by no means rules out the efficacy of homoeopathic simillimum for the treatment of AD/HD, in fact it gives encouragement for the conducting of larger, more extensive research projects in this direction.

A vast number of parents and teachers are looking for safe, effective treatment for AD/HD (Soreff & Chang, 2008), as well as for other behavioural disorders in children. This double-blind placebo-controlled study has aided in bringing to light homoeopathic simillimum treatment as one of those treatment options. Due to the tremendous variations in the behaviours, personalities, and characteristics of children diagnosed with AD/HD, individualised treatment is highly recommended (Reichenberg-Ullman & Ullman, 2000). Homoeopathy provides the individualised treatment and holistic approach that these children need to support and help them cope with their disorder and the demands of developing into healthy, well-adjusted adults in this modern day.

## **RECOMMENDATIONS**

Many experts think that AD/HD is overdiagnosed, largely because criteria (DSM-IV-TR, Appendix A) are applied inaccurately (Beers, 2006 pg 2483). Comprehensive diagnosis would be recommended for each participant entering into the study to ensure that diagnostic criteria are fulfilled. In this study participants had to be pre-diagnosed by a child psychologist or paediatrician but even though this criterion was applied, misdiagnosis was still suspected in some of the cases, as the participants did not seem to fulfil

AD/HD criteria (Appendix A). A costly recommendation that would reduce the variable of misdiagnosis would be to involve professional experts in the field of AD/HD in the study and only accept participants diagnosed by them. Another option would be to insist that participants have 2 diagnoses from professionals such as paediatricians, neurologists, psychologists or occupational therapists. Further studies could also be conducted that focus on particular subtypes of AD/HD. This would make finding participants more difficult but would be more likely to ensure accurate diagnoses.

Ideally, studies involving treatment with simillimum should be carried out by experienced practitioners. They should be experienced both in simillimum prescribing and the specific sample group or disorder that is being studied. This would decrease the variable of an inexperienced practitioner. To lessen the chance of conducting a placebo-controlled simillimum trial with the incorrect simillimum, a study design like Frei *et al.*'s (2007) whereby treatment with simillimum is carried out until the participant reaches a pre-defined level of improvement should be implemented. After participants reach this level they are then randomly divided into a treatment and a placebo group and this second phase of the study is conducted as a double-blind placebo-controlled study, with treatment being the individual's pre-determined simillimum. This would mean a very long-duration study but a far more accurate method of comparing simillimum with placebo. It would also lessen the impact of being in the placebo group, for the participants, as they would have had successful treatment before, and the placebo period was of a relatively short duration (6 weeks), compared to the treatment period (mean time of 5 months). The current study could not be conducted in this manner due to time and budget constraints. Although generally ethically unsound, a study design incorporating a non-intervention group could eliminate the complication of placebo effect improvements.

The sample group was small in this study due to patient compliance, and time and budget constraints. A larger study (e.g. 100 participants) with a longer duration (e.g. 1 year) would produce more significant results.

In spite of the reliability and validity of DSM-IV symptom rating scales (such as ADHD Rating Scale-IV [Appendices B and C], used in this study), as a useful metric for evaluating and monitoring treatment effects, this approach has limitations. From a clinical perspective, the reasons patients seek treatment are clearly only secondarily related to the specific symptoms. In other words, it is not the symptoms themselves that lead patients to our offices, but rather the wide range of idiosyncratic functional impairments that arise in day-to-day living. By considering the broader context of impairment when evaluating treatment effects, clinicians can potentially be more effective at individualizing interventions (Kollins, 2007). Use of a combined quantitative and qualitative approach in evaluating results is recommended. Quantitative results show the amount of improvement whereas qualitative results show the nature of the improvement (Dirckx, 2001). Incorporating qualitative data would ensure a more rounded evaluation of the outcomes of the study. A recommendation would be to incorporate a Quality of Life rating scale such as the Child's Health Questionnaire (available at <http://www.healthact.com/chq.html>), into the study, as it may capture more general, or other improvements described in Chapter 5.

In terms of utilising home and school versions of scales, more care could be used in ensuring uniformity in the application of the rating scales to further decrease the disparity between the results of the home and school versions. The researcher could either ask the parent/guardian to complete the rating scale before proceeding with any discussion about the case or, alternatively, could meet with the teacher when he/she completes the scale.

Teacher education about homoeopathy and how it differs to the allopathic approach would be useful to sensitise the teacher to notice more subtle

changes, and changes on other levels in the child. This would lead to a more detailed and accurate school assessment.

Increasing the time period of cessation of other natural or orthodox treatment before commencing the study is recommended. This study only specified 1-week of ceased treatment but it is felt by the researcher that increasing this time period would give the parents and researcher a clearer picture of the child's baseline state. Frei *et al.* (2007) noted in their randomised controlled trials of homoeopathy in hyperactive children that patients pre-treated with stimulants were more difficult to treat with homoeopathy and could be an obstacle in a double-blind clinical trial. This obstacle could be removed if participants were limited to those who had never taken allopathic medication for their AD/HD symptoms.

Another obstacle to cure was the family dynamics seen in most cases. A study involving a family approach to treatment could lead to a more significant treatment outcome.

The diagnosis of Adult AD/HD is becoming more common and a study addressing this group would further the credibility of homoeopathic treatment for AD/HD.



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## APPENDIX A

The **DSM-IV Diagnostic Criteria** for Attention Deficit/Hyperactivity Disorder is:

A. Either (1) or (2):

(1) six or more of the following symptoms of inattention have persisted for at least 6 months to a degree that is maladaptive and inconsistent with developmental levels:

*Inattention*

- a) often fails to give close attention to details or makes careless mistakes in schoolwork, work, or other activities.
- b) often has difficulty sustaining attention in tasks or play activities
- c) often does not seem to listen when spoken to directly
- d) often does not follow through on instructions and fails to finish school-work, chores, or duties in the workplace (not due to oppositional behaviour or failure to understand instructions)
- e) often has difficulty organizing tasks and activities
- f) often avoids, dislikes, or is reluctant to engage in tasks that require sustained mental effort (such as school-work or homework)
- g) often loses things necessary for tasks or activities (e.g. toys, school assignments, pencils, books, or tools)
- h) is often easily distracted by extraneous stimuli
- i) is often forgetful in daily activities

(2) six (or more) of the following symptoms of hyperactivity-impulsivity have persisted for at least 6 months to a degree that is maladaptive and inconsistent with developmental level

*Hyperactivity*

- a) often fidgets with hands or feet or in situations in which remaining seated is expected.
- b) often leaves seat in classroom or in other situations in which remaining seated is expected
- c) often runs about or climbs excessively in situations in which it is inappropriate (in adolescent or adults, may be limited to subjective feelings of restlessness)
- d) often has difficulty playing and engaging in leisure activities quietly
- e) is often "on the go" or often acts as if "driven by a motor"
- f) often talks excessively

*Impulsivity*

- a) often bursts out answers before questions have been completed
- b) often has difficulty awaiting turn
- c) often interrupts or intrudes on others (e.g. butts into conversations or games)

B. Some hyperactive-impulsive or inattention symptoms that caused impairment were present before age 7 years.

C. Some impairment from the symptoms is present in two or more settings (e.g. at school [or work] and at home)

D. There must be clear evidence of clinically significant impairment in social, academic, or occupational functioning.

E. The symptoms do not occur exclusively during the course of a Pervasive Developmental Disorder, Schizophrenia, or other Psychotic Disorders and are not better accounted for by another mental disorder (e.g. Mood Disorder, Anxiety Disorder, Dissociative Disorder, or a Personality Disorder).

*Code based on type:*

**314.01 Attention-Deficit/Hyperactivity Disorder, Combined Type:**

if both Criteria A1 and A2 are met for the past 6 months

**314.00 Attention-Deficit/Hyperactivity Disorder, Predominantly Inattentive Type:** if Criterion A1 is met but Criterion A2 is not met for the past 6 months

**314.01 Attention-Deficit/Hyperactivity Disorder, Predominantly Hyperactive-Impulsive Type:** if Criterion A2 is met but Criterion A1 is not met for the past 6 months

**Coding note:** For individuals (especially adolescents and adults) who currently have symptoms that no longer meet full criteria, “In Partial Remission”

## APPENDIX B

### ADHD RATING SCALE-IV: HOME VERSION

Child's name \_\_\_\_\_ Sex: M F Age \_\_\_\_\_ Grade \_\_\_\_\_

Completed by: Mother \_\_\_\_\_ Father \_\_\_\_\_ Guardian \_\_\_\_\_ Grandparent \_\_\_\_\_

Circle the number that *best describes* your child's home behavior over the past 6 months.

	Never or rarely	Sometimes	Often	Very often
1. Fails to give close attention to details or makes careless mistakes in schoolwork.	0	1	2	3
2. Fidgets with hands or feet or squirms in seat.	0	1	2	3
3. Has difficulty sustaining attention in tasks or play activities.	0	1	2	3
4. Leaves seat in classroom or in other situations in which remaining seated is expected.	0	1	2	3
5. Does not seem to listen when spoken to directly.	0	1	2	3
6. Runs about or climbs excessively in situations in which it is inappropriate.	0	1	2	3
7. Does not follow through on instructions and fails to finish work.	0	1	2	3
8. Has difficulty playing or engaging in leisure activities quietly.	0	1	2	3
9. Has difficulty organizing tasks and activities.	0	1	2	3
10. Is "on the go" or acts as if "driven by a motor."	0	1	2	3
11. Avoids tasks (e.g., schoolwork, homework) that require sustained mental effort.	0	1	2	3
12. Talks excessively.	0	1	2	3
13. Loses things necessary for tasks or activities.	0	1	2	3
14. Blurts out answers before questions have been completed.	0	1	2	3
15. Is easily distracted.	0	1	2	3
16. Has difficulty awaiting turn.	0	1	2	3
17. Is forgetful in daily activities.	0	1	2	3
18. Interrupts or intrudes on others.	0	1	2	3

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## APPENDIX C

### ADHD RATING SCALE-IV: SCHOOL VERSION

Child's name \_\_\_\_\_ Sex: M F Age \_\_\_\_\_ Grade \_\_\_\_\_  
 Completed by: \_\_\_\_\_

Circle the number that *best describes* this student's school behavior over the past 6 months (or since the beginning of the school year).

	Never or rarely	Sometimes	Often	Very often
1. Fails to give close attention to details or makes careless mistakes in schoolwork.	0	1	2	3
2. Fidgets with hands or feet or squirms in seat.	0	1	2	3
3. Has difficulty sustaining attention in tasks or play activities.	0	1	2	3
4. Leaves seat in classroom or in other situations in which remaining seated is expected.	0	1	2	3
5. Does not seem to listen when spoken to directly.	0	1	2	3
6. Runs about or climbs excessively in situations in which it is inappropriate.	0	1	2	3
7. Does not follow through on instructions and fails to finish work.	0	1	2	3
8. Has difficulty playing or engaging in leisure activities quietly.	0	1	2	3
9. Has difficulty organizing tasks and activities.	0	1	2	3
10. Is "on the go" or acts as if "driven by a motor."	0	1	2	3
11. Avoids tasks (e.g., schoolwork, homework) that require sustained mental effort.	0	1	2	3
12. Talks excessively.	0	1	2	3
13. Loses things necessary for tasks or activities.	0	1	2	3
14. Blurts out answers before questions have been completed.	0	1	2	3
15. Is easily distracted.	0	1	2	3
16. Has difficulty awaiting turn.	0	1	2	3
17. Is forgetful in daily activities.	0	1	2	3
18. Interrupts or intrudes on others.	0	1	2	3

From *ADHD Rating Scale-IV: Checklists, Norms, and Clinical Interpretation* by George J. DuPaul, Thomas J. Power, Arthur D. Anastopoulos, and Robert Reid. Copyright 1998 by the authors. Permission to photocopy this scale is granted to purchasers of *ADHD Rating Scale-IV* for personal use only (see copyright page for details). ADHD criteria are adapted by permission from DSM-IV. Copyright 1994 by the American Psychiatric Association.

## **APPENDIX D**

### **TELEPHONIC DISCUSSION**

- Is your child between the ages of 6-11 years?
- Is your child fluent in English?
- Has your child been diagnosed with ADD or ADHD by a child psychologist or paediatrician?
- Is your child on any medication, orthodox or natural, for the conditions?
- Is your child on any chronic medication for any other condition?
- Has your child been diagnosed with any other mental or behavioural disorders? Eg. Mood Disorder, Anxiety Disorder or Personality Disorder.

## **APPENDIX E**

### **PARENT/GUARDIAN AND TEACHER SUBJECT INFORMATION LETTER**

#### **TITLE OF RESEARCH PROJECT:**

*A double-blind, placebo-controlled study on the relative efficacy of homoeopathic similimum in the treatment of Attention Deficit Disorder (ADD) and Attention Deficit Hyperactivity Disorder (ADHD) in schoolgoing children.*

#### **SUPERVISOR:**

Dr Corne Hall M. Tech (Hom); B.Sc (PU for C.HE)

#### **JOINT-SUPERVISOR:**

Dr Ingrid Couchman M.Tech (Hom)

#### **RESEARCH STUDENT:**

Megan Jones

Dear Parent/Guardian and Teacher,

Firstly, thank-you for your time and interest in this research study. With your assistance the effectiveness of Homoeopathic treatment for children with ADD and ADHD can be investigated in the hopes that more children with this disorder can be treated in a natural, drug-free way.

I am a 5<sup>th</sup> year homoeopathic student at Durban University of Technology (DUT) and in order to qualify as a homoeopath I have to complete a mini-dissertation. This will take the form of a clinical trial will be conducted over a period of 2 months at the DUT Homoeopathic Day Clinic in afternoon sessions, under the supervision of a qualified and registered homoeopath.

Participants must fulfil the following selection criteria in order to participate in the study:

1. Must be fluent in English.
2. Must be between the ages of 6-11 years.
3. Must be diagnosed, according to DSM-IV Criteria with ADD or ADHD by a child psychologist or paediatrician.
4. Must not be currently taking any ADD or ADHD medication, orthodox or natural.

Participants with the following criteria will be excluded from the study:

1. Children on chronic medication for another condition.
2. Children with other mental or behavioural disorders.
3. Children who is on treatment for ADD or ADHD.

If your child fulfils the selection criteria and you are both willing to participate in the study, your child will be accepted into the study group. The study will run over 2 months. Parents and participants will be required to attend three consultations during that time. At each consultation you will be required to fill in a standard ADD/ADHD rating scale. The initial consultation will take 1 hour

and the follow-up consultations will take 30 minutes. Teachers are required to fill in a teacher version of the standard ADD/ADHD rating scales, which will be sent to school with the participant.

This trial is a placebo-controlled study, which means that 50% of participants will be given placebo. Placebo medication looks and tastes exactly the same as the treatment medication but has no action and is neutral. During the study you and I will not know if your child is in the treatment or placebo group. Only the supervisor will know which group your child is in. Those receiving placebo will be offered free treatment at the end of the study.

All participant information will be kept strictly confidential and participants will be referred to as numbers only in the study. Patient information will be kept in a locked drawer at the Homoeopathic Day Clinic and this information will be stored for 5 years after the study, after which time it will be destroyed.

Your participation in this study is entirely voluntary and the treatment and consultation costs will be covered by the DUT.

You are free to withdraw your child from the study at any point without prejudices and consequences, and without giving reasons.

The risk involved in the study is delayed improvement of your child's condition if they are in the placebo group. The benefits include free consultations and treatment at the Homoeopathic Day Clinic and the improvement of your child's condition if they are in the treatment group.

If you have any questions or concerns about the study please feel free to contact any of the supervisors or myself.

Many thanks for your valued attention.

---

Megan Jones  
(5<sup>th</sup> Year Homoeopathy Student)

Tel. 031 209 1530  
Cel: 0842485825

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Dr Corne Hall  
(Research Supervisor)

Tel. 031 373 2041



## APPENDIX F

### INFORMED CONSENT FORM

#### **TITLE OF RESEARCH PROJECT:**

*A double-blind, placebo-controlled study on the relative efficacy of homoeopathic similimum in the treatment of Attention Deficit Disorder (ADD) and Attention Deficit Hyperactivity Disorder (ADHD) in schoolgoing children.*

#### **SUPERVISOR:**

Dr Corne Hall M. Tech (Hom); B.Sc (PU for C.HE)

#### **JOINT-SUPERVISOR:**

Dr Ingrid Couchman M. Tech (Hom)

#### **RESEARCH STUDENT:**

Megan Jones

#### **PLEASE CIRCLE THE APPROPRIATE ANSWERS:**

- |   |          |
|---|----------|
| 1. Have you read the research information sheet?  | Yes / No |
| 2. Have you had the opportunity to ask questions regarding this study?  | Yes / No |
| 3. Have you received satisfactory answers to your questions?  | Yes / No |
| 4. Do you understand the nature of this research project and its structure?   | Yes / No |
| 5. Do you understand that participants are free to withdraw from the study at any time, without having to offer a reason?   | Yes / No |
| 6. Do you agree not to discuss any of the particulars of your child's treatment with any other study participants you may come into contact with for the duration of the study? | Yes / No |
| 7. Do you agree to allow the child under your care to participate in the study?   | Yes / No |

If you have answered no to any of the questions above please consult the researcher before signing.

I, \_\_\_\_\_, the undersigned, as parent/  
guardian hereby give consent for \_\_\_\_\_  
\_\_\_\_\_ to participate in the above  
mentioned study.

\_\_\_\_\_  
Signature parent/ guardian

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness signature

\_\_\_\_\_  
Date

## APPENDIX G

### PARTICIPANT SUBJECT INFORMATION LETTER

Dear Participant,

Welcome to this study and thank-you for taking part. By taking part you may be helping yourself and other children who are the same as you. This letter has been written to make sure you understand what the study is all about.

The reason we are doing this study is to see how homoeopathy can help in the treatment of Attention Deficit Disorder (ADD) and Attention Deficit Hyperactivity Disorder (ADHD), or Hyperactivity, as you may know it. Children with ADD and ADHD often have difficulty concentrating or battle to finish their school-work on time.

Homoeopathy is a type of natural medicine that helps the body to heal itself. It is safe for children.

The study will run over 2 months, during which time you will come to the Homoeopathic Day Clinic with your parent for 3 visits with me. During the visits I'll just be asking questions to get to know you. Your parent and teacher will fill out forms so that we can monitor how you've been doing. You will be given some powders and drops to be taken every day.

In this study we have a placebo group. A placebo is a something that looks and tastes like the medicine but it isn't a medicine and it doesn't do anything. Half of the children in the study will be given placebo instead of medicine. The only person who will know who is given placebo is the person who makes the medicine. If you are one of the children who get placebo we will give you the real medicine free of charge after the study.

Please feel free to ask any questions you may have and remember that you are allowed to leave the study at any point, without giving reasons.

Thank-you for taking part in this study.

---

Megan Jones  
(5<sup>th</sup> Year Homoeopathic Student)

---

Dr Corne Hall  
(Research Supervisor)

## APPENDIX H

### MINOR ASSENT FORM

My name is \_\_\_\_\_

- I would like to be part of this research project.
- The project has been explained to me.
- I am not being forced to take part in the project.
- I understand that I can decide to stop being in the project at any time.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

## APPENDIX I

### HOMOEOPATHIC CASE HISTORY

#### PATIENT'S DETAILS:

Name: \_\_\_\_\_ Date: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

Date of Birth: \_\_\_\_\_ Age: \_\_\_\_\_

Sex: \_\_\_\_\_

Tel.: \_\_\_\_\_

#### PARENT/ GUARDIAN DETAILS:

Name: \_\_\_\_\_

Tel.: (H) \_\_\_\_\_ (W) \_\_\_\_\_

MAIN COMPLAINT: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

PAST MEDICAL HISTORY AND TX (incl. childhood diseases, vaccinations):

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

FAMILY HISTORY: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

BIRTH HISTORY:

Pregnancy \_\_\_\_\_

\_\_\_\_\_

Labour \_\_\_\_\_

MILESTONES: \_\_\_\_\_

GENERALS:

Sleep: \_\_\_\_\_

Weather: \_\_\_\_\_

SYSTEMS:

Head: \_\_\_\_\_

ENT: \_\_\_\_\_

Respiratory: \_\_\_\_\_

GIT: \_\_\_\_\_

Diet: \_\_\_\_\_

Cravings/ Aversions: \_\_\_\_\_

Appetite: \_\_\_\_\_

Thirst: \_\_\_\_\_

Stool: \_\_\_\_\_

Genito-urinary: \_\_\_\_\_

Urine: \_\_\_\_\_

Discharges: \_\_\_\_\_

Musculoskeletal: \_\_\_\_\_

\_\_\_\_\_

Skin: \_\_\_\_\_

\_\_\_\_\_

Perspiration: \_\_\_\_\_

PERSONALITY: Temperament: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Relations with others: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Fears: \_\_\_\_\_

\_\_\_\_\_

COMMENTS AND OBSERVATIONS: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

## APPENDIX J

### PHYSICAL EXAMINATION:

#### VITAL SIGNS:

Temperature: \_\_\_\_\_

Respiratory rate: \_\_\_\_\_

Height: \_\_\_\_\_

Pulse: \_\_\_\_\_

BP: \_\_\_\_\_

Weight: \_\_\_\_\_

#### GENERAL EXAMINATION:

Jaundice, anaemia, cyanosis, clubbing, dehydration, lymphadenopathy:

---

---

ENT: \_\_\_\_\_

---

---

RESPIRATORY: \_\_\_\_\_

---

---

CARDIOVASCULAR: \_\_\_\_\_

---

---

ABDOMINAL: \_\_\_\_\_

---

---

NEUROLOGICAL: \_\_\_\_\_

---

---

---

## APPENDIX K

### RESEARCH PROJECT

Please join us in assisting with the current research project.

Megan Jones, a Master's Homoeopathy student at the Durban University of Technology is conducting a clinical trial on:

***“The efficacy of homoeopathic similimum in the treatment of Attention Deficit Disorder (ADD) and Attention Deficit Hyperactivity Disorder (ADHD) in schoolgoing children aged 6-11 years.”***

This will take the form of a clinical trial, conducted at the Homoeopathic Day Clinic at the Durban University of Technology. The trial will run over a two month period. Treatment will be free.

Inclusion criteria:

- i. Participants must be between the ages of 6-11 years at the start of the study.
- ii. Participants must be fluent in English.
- iii. Participants must be pre-diagnosed by a child psychologist or paediatrician.
- iv. Participants must not currently be taking any medication, orthodox or natural, for ADD or ADHD.

Participation will involve attending three consultations with Megan at the Homoeopathic Day Clinic and taking the prescribed homoeopathic medicine. At each visit parents will be asked to complete a questionnaire and the child's teacher will be required to complete questionnaires for the child too.

Half the participants in the study will receive placebo but free treatment at the clinic is offered to participants in the placebo group after the study.

Homoeopathy is a safe and effective system of medicine that offers relief for a wide range of conditions.

Participation is entirely voluntary. If you would like to partake in the trial please contact Megan on **0842485825** or **031 2091530**.

**Ethical research projects guarantee confidentiality, informed consent and preventing psychological harm to participants. These are always part of our research projects and obviously will apply for the above.**





## **Does your child suffer from ADD?**

(ATTENTION DEFICIT DISORDER) OR

## **ADHD?**

(ATTENTION DEFICIT HYPERACTIVITY DISORDER)

They may qualify for **free treatment** which is currently being conducted at Durban University of Technology Homoeopathic Department.

### **REQUIREMENTS:**

- Between ages 6-11years
- English speaking

For more information please contact:

**Megan Jones**

084 248 5825 • 031 209 1530

**Research in  
Homoeopathy**


**Does your child suffer from**  
**ADD**  
**(ATTENTION DEFICIT DISORDER)**  
**OR**  
**ADHD?**  
**(ATTENTION DEFICIT HYPERACTIVITY DISORDER)**

**They may qualify for free treatment which is currently  
being conducted at Durban University of Technology  
Homoeopathic Department.**

**REQUIREMENTS:**

- **Between ages 6-11years**
- **English speaking**

**For more information please contact:**  
**MEGAN JONES**  
**084 248 5825 • 031 209 1530**

 **DURBAN  
UNIVERSITY of  
TECHNOLOGY**  
*A Leading University of Technology in Africa*

## APPENDIX N: RUBRICS AND REPERTORY SHEETS

All repertorisation done using Radar Version 9.0 Homeopathic Software for Windows

CASE 1:

### SCRIPT:

Rx: Sulphur 200CH

Mitte: iii pulv.

Sig: o.n.

(2<sup>nd</sup> script: Sulphur 200CH)

### RUBRICS:

MIND - RESTLESSNESS - children, in

MIND - DICTATORIAL

MIND - DEFIANT

MIND - FEAR - dark; of

GENERALS - FOOD and DRINKS - eggs - desire

SLEEP - POSITION - side; on - left side; on

STOMACH - THIRST

RECTUM - CONSTIPATION - children, in

### REPERTORY SHEET:

		sulph.	caust.	calc.	lyc.	acon.	merc.	phos.	nux-v.	sep.
		1	2	3	4	5	6	7	8	9
Sum of symptoms (sort:deg)		8 12	7 13	6 13	6 12	6 11	6 11	6 10	6 9	6 7
01. MIND - RESTLESSNESS - children, in	2	1	1	2	1	3	3	1	1	-
02. MIND - DICTATORIAL	1	2	1	-	3	-	2	1	1	1
03. MIND - DEFIANT	1	1	3	-	2	1	1	-	1	1
04. MIND - FEAR - dark; of	1	1	2	2	2	2	1	2	1	1
05. GENERALS - FOOD and DRINKS - eggs - desir	1	1	1	2	-	-	-	1	-	-
06. SLEEP - POSITION - side; on - left side; on	1	2	-	1	-	1	1	2	-	1
07. STOMACH - THIRST	1	3	3	3	1	3	3	3	2	1
08. RECTUM - CONSTIPATION - children, in	1	1	2	3	3	1	-	-	3	2

## CASE 2:

### SCRIPT:

Rx: Calcareum phosphoricum 30CH plussed

Mitte: 24ml

Sig: 10 gtt. after viii succussions

(2nd script: Phosphoricum acidum 200CH & 200CH plussed)

### RUBRICS:

MIND - FEAR - falling, of

MIND - INDIFFERENCE

MIND - PROSTRATION of mind

STOMACH - THIRST

EXTERNAL THROAT - SWELLING - Cervical Glands

GENERALS - HEAT - lack of vital heat

GENERALS - FOOD and DRINKS - fruit - desire

SLEEP - POSITION - back, on

### REPERTORY SHEET:

		phos.	calc.	puls.	nat-m.	chin.	zinc.	sulph.	sil.	lyc.
		1	2	3	4	5	6	7	8	9
Sum of symptoms (sort:deg)		8	8	8	8	8	8	7	7	7
		18	17	17	15	14	10	17	16	14
01. MIND - FEAR - falling, of	1	1	1	2	1	1	1	-	1	1
02. MIND - INDIFFERENCE	1	3	2	3	3	3	1	2	2	2
03. MIND - PROSTRATION of mind	2	3	2	2	2	1	2	3	3	3
04. STOMACH - THIRST	1	3	3	1	3	3	2	3	3	1
05. EXTERNAL THROAT - SWELLING - Cervical G	1	2	3	2	2	2	1	3	3	3
06. GENERALS - HEAT - lack of vital heat	1	3	3	2	2	2	1	2	3	2
07. GENERALS - FOOD and DRINKS - fruit - desire	1	1	1	1	1	1	1	1	1	-
08. SLEEP - POSITION - back, on	1	2	2	4	1	1	1	3	-	2



### CASE 3:

#### SCRIPT:

Rx: Hyoscyamus M

Mitte: iii pulv

Sig: o.d.

(2<sup>nd</sup> script: Tuberculinum bovinum 30CH, 200CH, M)

#### RUBRICS:

MIND - DESTRUCTIVENESS - children; in

MIND - GESTURES, makes - ridiculous or foolish

MIND - ANGER - violent

MIND - RESTLESSNESS - busy

MIND - COMPANY - desire for

MIND - FEAR - dark; of

GENERALS - RIDING - car, in a - agg.

GENERALS - FOOD and DRINKS - cheese - desire

VISION - COLORS before the eyes

#### REPERTORY SHEET:

		hyos.	phos.	sep.	nux-v.	bell.	stram.	calc.	kali-c.	lyc.
		1	2	3	4	5	6	7	8	9
Sum of symptoms (sort:deg)		9	7	7	7	7	6	6	6	6
		14	12	12	11	10	11	10	10	10
01. MIND - DESTRUCTIVENESS - children; in	2	1	1	-	-	-	1	-	-	-
02. MIND - GESTURES, makes - ridiculous or foolis	1	3	-	2	1	2	2	-	-	-
03. MIND - ANGER - violent	1	2	1	2	4	2	1	2	2	2
04. MIND - RESTLESSNESS - busy	2	1	-	-	1	1	-	-	-	-
05. MIND - COMPANY - desire for	1	3	4	2	2	1	2	2	3	3
06. MIND - FEAR - dark; of	1	1	2	1	1	1	4	2	1	2
07. GENERALS - RIDING - car, in a - agg.	1	1	1	3	1	1	-	1	1	1
08. GENERALS - FOOD and DRINKS - cheese - de	1	1	2	1	-	-	-	1	1	1
09. VISION - COLORS before the eyes	1	1	1	1	1	2	1	2	2	1

# CASE 4:

## SCRIPT:

Rx: Sulphur M

Mitte: iii pulv

Sig: o.m.

(1st script: Tuberculinum bovinum M)

## RUBRICS:

MIND - RESTLESSNESS

MIND - DICTATORIAL

MIND - CONFIDENT

GENERALS - FOOD and DRINKS - farinaceous - desire

GENERALS - FOOD and DRINKS - vegetables - desire

SLEEP - POSITION - back, on

BLADDER - URINATION - involuntary - night

## REPERTORY SHEET:

		sulph.	lyc.	nux-v.	phos.	verat.	puls.	alum.	ars.	cupr.
		1	2	3	4	5	6	7	8	9
Sum of symptoms (sort:deg)		7	6	6	6	6	5	5	5	5
		15	13	10	9	7	12	9	9	8
01. MIND - RESTLESSNESS	2	3	3	2	1	1	3	1	3	3
02. MIND - DICTATORIAL	1	2	3	1	1	1	1	-	1	2
03. MIND - CONFIDENT	1	1	1	1	-	1	-	2	-	-
04. GENERALS - FOOD and DRINKS - farinaceous	1	2	1	1	1	-	1	2	-	-
05. GENERALS - FOOD and DRINKS - vegetables -	1	2	-	-	1	1	-	2	1	1
06. SLEEP - POSITION - back, on	1	3	2	3	2	1	4	-	1	1
07. BLADDER - URINATION - involuntary	1	2	3	2	3	2	3	2	3	1

CASE 5:

SCRIPT:

Rx: Calcareum sulphuricum 200CH

Mitte: iii pulv

Sig: o.m

(2<sup>nd</sup> script: Calcareum sulphuricum 200CH plussed)

RUBRICS:

MIND - IRRITABILITY

GENERALS - HEAT - sensation of

GENERALS - FOOD and DRINKS - farinaceous - desire

GENERALS - FOOD and DRINKS - fat - desire

HEAD - PERSPIRATION of scalp

STOMACH - THIRST - night

STOMACH - THIRSTLESS - daytime

REPERTORY SHEET:

		calc.	sulph.	nit-ac.	phos.	puls.	nat-m.	nux-v.	sil.	lyc.
		1	2	3	4	5	6	7	8	9
Sum of symptoms (sort:deg)		6 13	6 13	6 12	6 12	6 12	6 11	6 10	5 14	5 11
01. MIND - IRRITABILITY	1	3	3	3	3	3	3	3	3	3
02. GENERALS - HEAT - sensation of	1	2	3	2	2	3	3	2	3	3
03. GENERALS - FOOD and DRINKS - farinaceous	1	2	2	1	1	1	2	1	-	1
04. GENERALS - FOOD and DRINKS - fat - desire	1	1	2	3	1	1	1	2	2	-
05. HEAD - PERSPIRATION of scalp	1	3	1	2	3	3	1	1	3	2
06. STOMACH - THIRST - night	1	2	2	1	2	1	1	1	3	2
07. STOMACH - THIRSTLESS - daytime	1	-	-	-	-	-	-	-	-	-



## CASE 6:

### SCRIPT:

Rx: Pulsatilla 30CH plussed

Mitte: 24ml

Sig: x gtt. after x succussions

(1<sup>st</sup> script: Pulsatilla LM1)

### RUBRICS:

MIND - BESIDE ONESELF; being

MIND - FEAR - animals, of

MIND - CONFIDENCE - want of self-confidence

GENERALS - FOOD and DRINKS - fruit - aversion

GENERALS - FOOD and DRINKS - ice cream - desire

GENERALS - HEAT - lack of vital heat

STOMACH - THIRST

SLEEP - RESTLESS

RESPIRATION - ASTHMATIC - night

### REPERTORY SHEET:

		puls.	phos.	sulph.	chin.	ars.	sil.	calc.	caust.	arg-n.
		1	2	3	4	5	6	7	8	9
Sum of symptoms (sort:deg)		9 18	9 17	9 17	7 17	7 16	7 16	7 13	7 13	7 12
01. MIND - BESIDE ONESELF; being	2	2	1	1	1	2	1	1	1	-
02. MIND - FEAR - animals, of	1	1	1	1	3	-	1	1	1	1
03. MIND - CONFIDENCE - want of self-confidence	1	2	1	1	2	1	3	1	1	1
04. GENERALS - FOOD and DRINKS - fruit - aversi	1	3	3	2	3	2	-	-	2	-
05. GENERALS - FOOD and DRINKS - ice cream -	1	1	3	2	-	-	2	2	-	1
06. GENERALS - HEAT - lack of vital heat	1	2	3	2	2	2	3	3	3	2
07. STOMACH - THIRST	1	1	3	3	3	3	3	3	3	3
08. SLEEP - RESTLESS	1	3	1	3	3	3	3	2	2	2
09. RESPIRATION - ASTHMATIC - night	1	3	1	2	-	3	-	-	-	2



CASE 7:

SCRIPT:

Rx: Calcarea sulphurica 30CH plussed

Mitte: 24ml

Sig: x gtt. after x succussions

(2<sup>nd</sup> script: Calcarea sulphurica 30CH plussed)

RUBRICS:

MIND - IRRITABILITY

RECTUM - CONSTIPATION

GENERALS - HEAT - sensation of

GENERALS - FOOD and DRINKS - fruit - desire

GENERALS - OBESITY

REPERTORY SHEET:

		nat-m.	calc.	sulph.	phos.	puls.	sil.	verat.	ant-c.	ars.
		1	2	3	4	5	6	7	8	9
Sum of symptoms (sort:deg)		5 13	5 12	5 12	5 11	5 11	5 11	5 11	5 10	5 10
01. MIND - IRRITABILITY	1	3	3	3	3	3	3	2	3	3
02. RECTUM - CONSTIPATION	1	3	3	3	3	2	3	3	1	3
03. GENERALS - HEAT - sensation of	1	3	2	3	2	3	3	2	2	1
04. GENERALS - FOOD and DRINKS - fruit - desire	1	1	1	1	1	1	1	3	2	1
05. GENERALS - OBESITY	1	3	3	2	2	2	1	1	2	2

# CASE 8:

## SCRIPT:

Rx: Phosphorus 30CH plussed

Mitte: 24ml

Sig: x gtt. after viii succussions

(2<sup>nd</sup> script: Phosphorus 30CH plussed)

## RUBRICS:

MIND - SOMNAMBULISM

MIND - FEAR - dark; of

MIND - FEAR - thunderstorm, of

MIND - FEAR - death, of

MIND - COMPANY - desire for

GENERALS - FOOD and DRINKS - chocolate - desire

GENERALS - FOOD and DRINKS - tomatoes - aversion

STOMACH - APPETITE - wanting

EXTREMITIES - PERSPIRATION - Foot - offensive

SLEEP - POSITION - changed frequently

## REPERTORY SHEET:

		phos.	lyc.	sulph.	calc.	nat-m.	sep.	kali-c.	ars.	puls.
		1	2	3	4	5	6	7	8	9
Sum of symptoms (sort:deg)		10 26	10 20	9 14	8 15	8 14	8 14	8 13	7 17	7 14
01. MIND - SOMNAMBULISM	1	3	1	2	1	3	1	1	-	-
02. MIND - FEAR - dark; of	1	2	2	1	2	1	1	1	1	2
03. MIND - FEAR - thunderstorm, of	1	4	2	1	1	2	2	-	-	-
04. MIND - FEAR - death, of	2	3	2	1	3	2	1	2	4	2
05. MIND - COMPANY - desire for	1	4	3	1	2	1	2	3	3	2
06. GENERALS - FOOD and DRINKS - chocolate - desire	1	2	2	2	1	1	2	1	2	1
07. GENERALS - FOOD and DRINKS - tomatoes - aversion	1	2	1	-	-	-	-	-	-	-
08. STOMACH - APPETITE - wanting	1	3	3	3	3	3	3	1	3	3
09. EXTREMITIES - PERSPIRATION - Foot - offensive	1	2	3	2	2	1	2	3	1	3
10. SLEEP - POSITION - changed frequently	1	1	1	1	-	-	-	1	3	1

## CASE 9:

### SCRIPT:

Rx: Silicea 30CH plussed

Mitte: 24ml

Sig: x gtt. after x succussions

(2<sup>nd</sup> script: Tuberculinum bovinum 200CH & 30CH plussed)

### RUBRICS:

MIND - TIMIDITY

MIND - GESTURES, makes - fingers - mouth; children put fingers into the

MIND - FEAR - dogs, of

MIND - FEAR - strangers, of

GENERALS - FOOD and DRINKS - eggs - desire

GENERALS - FOOD and DRINKS - ice cream - desire

GENERALS - HEAT - sensation of

### REPERTORY SHEET:

		sil.	puls.	calc.	sulph.	tub.	carc.	phos.	caust.	verat.
		1	2	3	4	5	6	7	8	9
Sum of symptoms (sort:deg)		7 13	6 13	6 12	6 11	6 8	6 7	5 10	5 7	5 6
01. MIND - TIMIDITY	1	4	4	3	3	1	1	3	2	1
02. MIND - GESTURES, makes - fingers - mouth; ch	1	1	-	2	1	-	-	-	-	1
03. MIND - FEAR - dogs, of	1	1	2	1	1	2	1	1	2	1
04. MIND - FEAR - strangers, of	1	1	1	-	-	1	1	-	1	-
05. GENERALS - FOOD and DRINKS - eggs - desir	1	1	2	2	1	1	2	1	1	-
06. GENERALS - FOOD and DRINKS - ice cream -	1	2	1	2	2	1	1	3	-	1
07. GENERALS - HEAT - sensation of	1	3	3	2	3	2	1	2	1	2

# CASE 10:

## SCRIPT:

Rx: Carcinosinum 30CH plussed

Mitte: 24ml

Sig: x gtt. after x succussions

(2<sup>nd</sup> script: Phosphorus 30CH plussed)

## RUBRICS:

MIND - MUSIC - desire for

MIND - AFFECTIONATE

MIND - FORSAKEN feeling

MIND - MILDNESS

GENERALS - FOOD and DRINKS - farinaceous - desire

GENERALS - FOOD and DRINKS - meat - desire

GENERALS - HEAT - sensation of

RECTUM - CONSTIPATION

## REPERTORY SHEET:

		aur.	carc.	nat-m.	puls.	sulph.	calc.	lyc.	phos.	positr.
		1	2	3	4	5	6	7	8	9
Sum of symptoms (sort:deg)		8 12	8 11	7 16	7 16	7 15	7 14	7 12	7 12	7 7
01. MIND - MUSIC - desire for	1	1	3	-	-	-	-	-	-	1
02. MIND - AFFECTIONATE	1	1	1	2	3	2	2	1	2	1
03. MIND - FORSAKEN feeling	2	3	1	2	3	1	1	1	1	1
04. MIND - MILDNESS	1	1	2	3	3	2	2	2	2	1
05. GENERALS - FOOD and DRINKS - farinaceous	1	1	1	2	1	2	2	1	1	1
06. GENERALS - FOOD and DRINKS - meat - desir	1	1	1	1	1	2	2	1	1	-
07. GENERALS - HEAT - sensation of	1	2	1	3	3	3	2	3	2	1
08. RECTUM - CONSTIPATION	1	2	1	3	2	3	3	3	3	1

# CASE 11:

## SCRIPT:

Rx: Veratrum album LM1

Mitte: 20ml

Sig: ii gtt. after viii succussions

(2<sup>nd</sup> script: continued with Veratrum LM1)

## RUBRICS:

MIND - VIOLENT

MIND - SUICIDAL disposition - throwing - windows, from

MIND - COMPANY - aversion to

MIND - RESTLESSNESS

MIND - UNFEELING

MIND - TACITURN

STOMACH - THIRST

GENERALS - FOOD and DRINKS - breakfast - aversion

GENERALS - HEAT - sensation of

## REPERTORY SHEET:

		verat.	sulph.	ars.	lach.	con.	thuj.	nat-m.	aur.	nux-v.
		1	2	3	4	5	6	7	8	9
Sum of symptoms (sort:deg)		9 16	8 20	8 14	8 14	8 12	8 12	7 17	7 16	7 16
01. MIND - VIOLENT	2	2	2	1	2	1	1	2	3	3
02. MIND - SUICIDAL disposition - throwing - window	2	1	2	2	1	-	1	-	3	1
03. MIND - COMPANY - aversion to	1	1	2	1	2	2	2	4	2	3
04. MIND - RESTLESSNESS	1	1	3	3	2	1	2	2	2	2
05. MIND - UNFEELING	2	1	2	1	2	1	-	1	-	-
06. MIND - TACITURN	1	3	3	2	1	1	2	2	3	3
07. STOMACH - THIRST	1	3	3	3	2	2	2	3	1	2
08. GENERALS - FOOD and DRINKS - breakfast - aversion	1	2	-	-	-	1	1	-	-	-
09. GENERALS - HEAT - sensation of	1	2	3	1	2	3	1	3	2	2



## CASE 12:

### SCRIPT:

Rx: Medorrhinum 200CH

Mitte: iii pulv

Sig: o.d.

Rx: Medorrhinum 30CH plussed

Mitte: 24ml

Sig: 10gtt, 10succ

(1<sup>st</sup> script: Tarentula hispanica 30CH plussed)

### RUBRICS:

MIND - JEALOUSY

MIND - RESTLESSNESS

MIND - DICTATORIAL

MIND - MEMORY - weakness of memory

MIND - STRIKING - children; in

DREAMS - DEAD; of the

RECTUM - CONSTIPATION

HEAD - PAIN - Forehead, in

### REPERTORY SHEET:

		lyc.	nux-v.	med.	kali-c.	ars.	sulph.	phos.	plat.	thuj.
		1	2	3	4	5	6	7	8	9
Sum of symptoms (sort:deg)		8 18	8 16	8 15	8 12	7 17	7 16	7 14	7 14	7 14
01. MIND - JEALOUSY	1	1	3	2	1	1	1	1	1	1
02. MIND - RESTLESSNESS	1	3	2	2	2	3	3	1	2	2
03. MIND - DICTATORIAL	1	3	1	2	1	1	2	1	2	1
04. MIND - MEMORY - weakness of memory	2	3	2	3	1	3	2	3	3	2
05. MIND - STRIKING - children; in	1	1	1	1	1	-	-	-	-	-
06. DREAMS - DEAD; of the	2	2	1	2	2	3	2	2	1	3
07. RECTUM - CONSTIPATION	1	3	3	1	2	3	3	3	3	3
08. HEAD - PAIN - Forehead, in	1	2	3	2	2	3	3	3	2	2

CASE 13:

SCRIPT:

Rx: Calcarea sulphurica 30CH plussed

Mitte: 24ml

Sig: x gtt. after x succussions

(1<sup>st</sup> script: Calcarea carbonica 30CH plussed)

RUBRICS:

MIND - SLOWNESS

MIND - FEAR - snakes, of

GENERALS - FOOD and DRINKS - meat - desire

GENERALS - FOOD and DRINKS - eggs - desire

STOMACH - THIRST

NOSE - DISCHARGE - clear

REPERTORY SHEET:

		calc.	sulph.	phos.	nat-m.	puls.	caust.	lach.	sep.	bell.
		1	2	3	4	5	6	7	8	9
Sum of symptoms (sort:deg)		6 11	6 11	5 9	5 8	5 8	4 6	4 6	4 6	4 5
01. MIND - SLOWNESS	1	2	3	3	1	3	1	1	3	1
02. MIND - FEAR - snakes, of	1	1	1	-	1	1	-	2	1	1
03. GENERALS - FOOD and DRINKS - meat - desir	1	2	2	1	1	1	1	1	1	-
04. GENERALS - FOOD and DRINKS - eggs - desir	1	2	1	1	-	2	1	-	-	-
05. STOMACH - THIRST	1	3	3	3	3	1	3	2	1	2
06. NOSE - DISCHARGE - clear	1	1	1	1	2	-	-	-	-	1

CASE 14:

SCRIPT:

Rx: Phosphorus 30CH plussed

Mitte: 24ml

Sig: x gtt. after x succussions

(1<sup>st</sup> script: Tarentula hispanica 200 CH)

RUBRICS:

MIND - CURIOUS

MIND - ABSENTMINDED - dreamy

MIND - RESTLESSNESS

MIND - SHRIEKING

GENERALS - FOOD and DRINKS - cold drink, cold water - desire

GENERALS - HEAT - sensation of

EXTREMITIES - WEAKNESS - Hand

SLEEP - POSITION - side; on - right side; on

REPERTORY SHEET:

		phos.	sulph.	positr.	lyc.	merc.	cham.	verat.	chin.	lach.
		1	2	3	4	5	6	7	8	9
Sum of symptoms (sort:deg)		8 16	8 14	8 8	7 15	7 13	7 12	7 12	7 11	7 10
01. MIND - CURIOUS	2	1	1	1	1	-	-	1	-	1
02. MIND - ABSENTMINDED - dreamy	1	3	1	1	-	1	1	1	1	2
03. MIND - RESTLESSNESS	1	1	3	1	3	3	2	1	2	2
04. MIND - SHRIEKING	1	2	2	1	3	1	2	3	2	1
05. GENERALS - FOOD and DRINKS - cold drink, c	1	3	1	1	2	3	3	3	3	-
06. GENERALS - HEAT - sensation of	1	2	3	1	3	2	2	2	1	2
07. EXTREMITIES - WEAKNESS - Hand	1	1	1	1	1	2	1	1	1	1
08. SLEEP - POSITION - side; on - right side; on	1	3	2	1	2	1	1	-	1	1



Case 15:

SCRIPT:

Rx: Lycopodium 30CH plussed

Mitte: 24ml

Sig: x gtt. after x succussions

(2<sup>nd</sup> script: Lycopodium 200CH & 30CH plussed)

RUBRICS:

MIND - LOQUACITY

MIND - WEEPING - easily

MIND - FEAR - alone, of being

MIND - AMBITION - increased - competitive

GENERALS - FOOD and DRINKS - chocolate - desire

GENERALS - FOOD and DRINKS - shellfish - agg.

GENERALS - FOOD and DRINKS - cold drink, cold water - agg.

GENERALS - FOOD and DRINKS - meat - aversion

GENERALS - HEAT - sensation of

NOSE - ITCHING - Inside

SKIN - DRY

REPERTORY SHEET:

		lyc.	puls.	calc.	arg-n.	bell.	ars.	nux-v.	sulph.	phos.
		1	2	3	4	5	6	7	8	9
Sum of symptoms (sort:deg)		10 21	9 18	9 16	9 14	9 14	8 16	8 14	7 17	7 15
01. MIND - LOQUACITY	2	1	1	1	1	2	1	1	1	2
02. MIND - WEEPING - easily	1	1	3	2	1	2	-	-	-	-
03. MIND - FEAR - alone, of being	1	3	2	1	3	1	3	1	-	3
04. MIND - AMBITION - increased - competitive	1	-	-	-	-	-	-	1	-	-
05. GENERALS - FOOD and DRINKS - chocolate - desire	1	2	1	1	1	-	2	-	2	2
06. GENERALS - FOOD and DRINKS - shellfish - agg.	1	2	-	-	-	1	-	-	-	-
07. GENERALS - FOOD and DRINKS - cold drink, cold water - agg.	1	2	1	1	1	2	2	2	2	-
08. GENERALS - FOOD and DRINKS - meat - aversion	1	2	3	3	2	1	2	3	3	2
09. GENERALS - HEAT - sensation of	1	3	3	2	2	1	1	2	3	2
10. NOSE - ITCHING - Inside	1	2	2	2	2	1	2	3	3	1
11. SKIN - DRY	1	3	2	3	1	3	3	1	3	3

