The relative efficacy of Advanced Brain Food® and a Homeopathic Complex (Quietude ®) in the management of Attention Deficit Hyperactivity Disorder (ADHD) in males between the ages of 8 and 13 years.

By

John-John Brian Lottering

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I John-John Brian Lottering do declare that this dissertation is representative of my own work, both in conception and execution.

Signature of Student **Date of signature**

APPROVED FOR FINAL SUBMISSION

Signature of Supervisor **Date of signature**

Dr. L. Strauss

M. Tech : Hom (TWR)

Signature of Joint-Supervisor **Date of signature**

Dr D.F. Naude

M. Tech : Hom (T.N)

ABSTRACT

The aim of the study was to evaluate the efficacy of a Nutritional Supplement (Advanced Brain Food®) and a homoeopathic complex (Quietude®) in the management of Attention Deficit Hyperactivity Disorder (ADHD). ADHD is primarily a childhood disorder affecting ten to twenty percent of school going children. The three main presenting features of ADHD are inattention, impulsivity, and hyperactivity. This triad often results in numerous adjustment difficulties for the child in the social and academic sectors (NIH Consensus Statement, 1998).

Current management of ADHD involves the administration of powerful drugs, of which the long-term value is questionable and the side effects common. Homoeopathy may offer an alternative in ADHD management that is free of side effects and safe to use over long periods. It was hypothesised that Quietude® and/or Advanced Brain Food® would result in an improvement in all aspects of ADHD, and could consequently be used as an alternative treatment for children diagnosed with ADHD.

The study was a randomized double blind clinical trial. Treatment was administered over a period of 6 weeks. The children involved in the trial completed a Children's Checking Task (Strauss, 2000) three times throughout the six-week trial period. The parent or guardian involved completed the Student Behaviour Log (Lazear, 1999) and ADHD Rating Scale (Du Paul, 1994) four times.

Twenty children diagnosed with ADHD were included in the study. Half of the children in the study received a Nutritional Supplement (Advanced Brain Food®) and the other half received a Homoeopathic Complex (Quietude®).

The raw data obtained from all the measurement tools were analyzed statistically by using non-parametric tests i.e. Friedman's for intra-group, and Mann-Whitney test for inter-group analysis. Non-parametric tests were chosen due to the small sample group. The results of the ADHD Rating Scale (Du Paul, 1991), Student Behaviour Log (Lazear, 1999) and Children's Checking Task (Strauss, 2000) were statistically analysed, using SPSS for Windows (SPSS Inc., Chicago, IL, USA). The alpha value was set at the 0.05 level of significance for all measurement tools used during this study.

The Children's Checking Task can be categorized into four groups, letters, numbers, symbols, and words. Each group evaluates a different component of mental functioning. An improvement in the overall test results i.e. increased scores (percentage) would indicate an increased sustained attention level (Strauss, 2000) Combined results for the Advanced Brain Food® and the Quietude® group across test one, two and three, using the Friedman test, revealed a significant difference in scores obtained by the Advanced Brain Food® group.

Group A showed a statistically significant result in three of the four components (letters, numbers and symbols) Using the inter-group test (Mann Whitney U-test), it was clear that there was only a difference between Group A (Advanced Brain Food®) and B (Quietude®) for letters at evaluation 3, Symbols at evaluation 3.i.e Group A was only shown to have superior score results in these two areas.

The ADHD Rating Scale (Du Paul, 1991) was used to evaluate inattention, hyperactivity and impulsitivity (Middleborough, 2001). The lower the number of points scored in each test, the more positive the results were, and vice versa.

Friedman's F test was used to perform an intra-group comparison for each of the groups on the four questionnaires that were completed. No statistically significant differences were noted for either of the groups. Inter-group analysis also revealed no statistical difference. Thus according to the data obtained from this measurement tool, both groups (Advanced Brain Food® group and Quietude group®) did not improve or regress significantly during the study period.

The Student Behaviour Log (Lazear, 1999) can be divided into the following major groupings- conduct problems, inattention, psychosomatic problems, impulsitivity-hyperactivity, and anxiety. The Student Behaviour Log (SBL) can also be scored for the hyperactivity index, which represents the overall measure of hyperactivity, taking into account

typical ADHD symptoms. The Friedman's test for both groups for all components of the SBL showed no difference over the study period ($P>0.05$) i.e. the two groups did not improve or regress significantly within themselves during the study. An intra-group analysis revealed significant P-values ($P< 0.05$) for conduct problems, inattention, psychosomatic problems and impulsitivity in the group taking Advanced Brain Food® during the six week trial period. There were however no statistically significant results obtained for hyperactivity and anxiety categories ($P>0.05$) during the trial period for both groups. It is clear that the group taking Advanced Brain Food® showed a significant improvement in the areas of conduct, inattention and impulsivity whereas the Quietude® group did not improve or regress during the trial period.

The findings using the SBL, suggest that Advanced Brain Food® resulted in an overall improvement in the clinical picture of ADHD when compared to the group taking Quietude® with regard to inattention, conduct problems, and impulsivity. According to the Children's Checking Task, Advanced Brain Food® is superior to Quietude® concerning an increased sustained level of attention. Even though an improvement was only seen in three areas during the study, a significant increase in any one of the areas point out that there is an improvement in the overall sustained level of attention (Strauss, 2000).

While all of the students in the trial met the diagnostic criteria for ADHD according to the DSM-V criteria (American Psychiatric Association, 1994) and Connor's Rating Scale as determined by a medical practitioner or psychologist, it can be concluded that some of these children need to be re-evaluated for ADHD due to the high incidence of mis-diagnosis of ADD/ADHD (NIH Consensus Statement, 1998).

Further it is important to remember that the results of this research are correlational. It is impossible to determine from the statistical data whether subjects who exhibit inattentive behaviour become underachievers or if underachievers exhibit inattentive behaviour.

From the results, it was apparent that both the Nutritional Supplement (Advanced Brain Food®) and the Homoeopathic Complex (Quietude®) were effective to a certain extent in decreasing some of the symptoms that a child with ADHD might demonstrate.

Consequently Advanced Brain Food® and/or Quietude® can be used in addition to cerebral stimulants, for example Ritalin®, or as an alternative natural treatment for the signs and symptoms of ADHD for those who do not wish to make use of orthodox medical intervention. If further studies are conducted in this field, it is recommended that a larger study group is to be used and both Advanced Brain Food® and Quietude® should be given simultaneously and compared to a placebo group.

Long-term follow-up studies after ten to twenty years could also yield needed results on the efficacy of long-term homoeopathic and/or naturopathic treatment in ADHD versus psychostimulant therapies.

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LIST OF ABBREVIATIONS

5-HT	5-Hydroxy Trypto
5-HTP	5-Hydroxytryptophan
ADD	Attention Deficit Disorder
ADHD	Attention Deficit Hyperactivity Disorder
BHA	Butylated Hydroxyanisole
BHT	Butylated Hydroxytoluene
CAARS-O:S	Conners Abbreviated Assessment Rating Scale: Observer
CAARS-S:L	Conners Abbreviated Assessment Rating Scale: Self Report
CADS	Connors Abbreviated Diagnostic Scale
CAT Scans	Computed Assisted Tomography
CGI-I Scale	Clinical Global Impression Scale
CNS	Central Nervous System
CoA	Co-enzyme A
CT Scan	Computed Tomography
C-T	Cytidylyl-Transferase
DGLA	Dihomolinoleic Acid
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders
EEGS	Electroencehalograms
EFA's	Essential Fatty Acids
GLA	Gamma Linolenic Acid
HDL	High Density Lipids
IQ	Intelligence Quotient

LDL	Low Density Lipids
MAO	Mono-amine Oxidaze
MRI's	Magnetic Resonance Imaging
MSG	Monosodium Glutamate
NGF	Nerve Growth Factor
NSS	Neurological Soft Signs
PC	Phosphatidylcholine
PET	Positron Emission Tomography
PGE_1	Prostaglandin E1
PS	Phosphatidylserine
RAS	Reticular Activating System
SKAMP Scale	Swanson, Kotkin, Atkins, M-Flynn and Pelham
SSRI's	Selective Serotonin Re-uptake Inhibitor's
VLDL	Very Low Density Lipids

DEFINITION OF TERMS

A. **Attention Deficit Hyperactivity Disorder (ADHD)–** a disorder of attention and impulse control with specific DSM-IV criteria, appears in childhood and may continue through to adulthood though it usually subsides during adolescence. Hyperactivity may be a feature but is not a requirement for diagnosis (Stedmann's Medical Dictionary, 1995).

B. Essential Fatty acid (EFA)– any long chain monobasic organic acid required for normal functioning of the human body and which must be obtained from a food source (Stedmann's Medical Dictionary, 1995).

C. **Hyperactivity –** muscular activity which is exaggerated considered to be inappropriate in terms of situation and excessive in duration (Picton, 1997). The hyperactive child shows a high level of mobility and inappropriate behaviour so that he or she is in constant conflict with the social environment (Kapp, 1991).

D. **Inattention** – a lack of attention or concerted effort in situations, which require extended concentration like performing a monotonous task such as reading or writing (Serfontein, 1990).

E. **Impulsivity –** sudden behaviour which is acted out without any thought with regards to consequences of the behaviour (Picton, 1997).

F. **Prostaglandin -** any of a class of physiologically active substances present in all tissues of the body with a broad range of effects which are local rather than systemic. Examples of effects are vasodilatation, vasoconstriction, smooth muscle control and control of membrane permeability of cells. The basic structure is

prostanoic acid, a twenty carbon fatty acid, with side chains of varying amounts of oxidation and unsaturation (Stedmann's Medical Dictionary, 1995).

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CHAPTER 1

INTRODUCTION

1.1 OVERVIEW

Attention-deficit hyperactivity disorder (ADHD) has been recognised in some form or other since the 1940s. Psychiatrists have applied various labels to children who are excessively active, lack attention and are impulsive. They have been variously labelled as having "minimal brain dysfunction", "brain-injured child syndrome", "hyperkinetic reaction of childhood", "hyperactive child syndrome", and most recently, "attention deficit disorder" (Leary, 1994).

These frequent name changes are good indications that no one really knows what is going on in this condition or even what the condition really comprises (Kaplan and Sadock, 1988).

Once thought to result from bad parenting or food allergies, it is now becoming apparent that there is a genetic basis to the disorder in children who genuinely have ADHD. At one stage people assumed that the main problem was that the child was unable to concentrate, so it was a disorder of attention itself. However, it is now becoming apparent that the lack of ability to concentrate is caused by a problem in the brain that controls inhibition and self control (Castellanos et al. 1996). This loss of self-control in turn negatively affects other brain functions, which are crucial for maintaining attention, and so the disorder develops (Frei et al. 2001).

ADHD is officially called Attention-Deficit/ Hyperactivity Disorder, or AD/HD (American Psychiatric Association, 1994) although most lay people, and even some professionals, still call it ADD or A.D.D. (the names given in 1980) or ADHD. The disorder's name has changed as a result of scientific advances and the findings of careful field trials (Gansler et al. 1998).

Today all forms of ADD/ADHD fall under the category of Attention Deficit Hyperactivity Disorder (ADHD), and then the main category is subdivided into ADHD Inattentive type, or ADHD Impulsive-Hyperactive Type (American Psychiatric Association, 1994). In the recent past the terms attention deficit disorder 'with' or 'without' hyperactivity were also commonly used (Berkow et al. 1992). Attention Deficit Hyperactivity Disorder comes in various forms, and truly, no two ADD or ADHD children are exactly alike (Gansler et al. 1998).

The National Institute of Health (NIH) Consensus Developmental Panel (1998) identifies the main presenting features of ADHD children, namely, inability to sustain attention, developmentally inappropriate levels of activity, distractibility and impulsivity. These symptoms often result in failure to interact well with family members and failure at school, both academically and socially (NIH Consensus Statement, 1998).

Today ADHD is the most common behavioural disorder seen by child psychiatrists (Holford, 2001) and is diagnosed in 40% of children seen by psychiatrists in the United Kingdom (Holford, 2001).

There is much controversy surrounding the diagnosis of ADD/ADHD, yet all of those involved in the treatment of these children agree that the numbers of affected children warrants serious attention (NIH Consensus Statement, 1998). It must be understood that it is during the formative years of a child's education that the most progress is made in intellectual development and the learning of principles of society. This is the same period where ADD/ADHD becomes most prevalent (Breggin, 2000). Any factor that hinders a child's progress in this period has a profound influence on the rest of society as it can lead to delinquency in later years and hence dependency on welfare structures (Holford 2001; Picton, 1997).

Despite progress in the assessment, diagnosis and treatment of ADD/ADHD, this disorder and its treatment have remained controversial, especially regarding the use of psychostimulants for both short- and long- term treatment (Karen et al.1997). Stimulant drugs e.g. Methylphenidate (Ritalin®) can cause psychosis in more than 9% of all individuals treated (Breggin, 2000). All stimulant drugs impair growth, not only by suppressing appetite, but also by disrupting growth hormone production (Karen et al. 1997; Holford, 2001). Furthermore these drugs have addiction and abuse potential, based on the capacity of these drugs to drastically and permanently change brain chemistry (Richardson, Hamley and Sassone, 2000).

Children with ADHD more often than not have one or more nutritional imbalances that, once identified and corrected, can dramatically improve their energy, focus, concentration and behaviour (Holford, 2002).

The main aim of this nutritional supplement (Advanced Brain Food®) is to try and correct nutritional imbalances and thereby aim to correct neurotransmitter imbalances that can be present in the brain of an ADHD subject (Holford, 2002).

Homoeopathy and supplementation with nutritional supplements like Advanced Brain Food® are two natural approaches that are firstly safe, and can be used in conjunction with one another. As yet very little research has been done on establishing the efficacy of these two approaches and this was the primary aim of this research project.

Two homoeopathic methods are used today which rely on homoeopathically prepared remedies applied in a different manner than the usual classical or clinical prescription methods (Jouanny, 1993). The approach which was chosen for this particular research is derived from the HEEL® theory of homotoxicology (Biotherapeutic Index, 2000). It relies on addressing a single problem within the individual, like a deficiency, and then administering a substance, which should correct this deficiency. The remedy that was used was prepared in a homoeopathic manner but the method of prescription is not according to the usual law of similars as in classical homoeopathy.

HEEL® products have been researched and shown to be capable of reducing deficiencies by administering the deficient substance in low dilutions as homoeopathically prepared medicines (Biotherapeutic index, 2000).

The rationale behind these treatments is that the treatment is not on a physical level; rather the homoeopathically prepared medicines have an energetic nature that stimulates the body and allows it to correct the deficiency using its own abilities.

This study focused specifically on the concentrational deficits and impulsivity aspects of the child's behaviour. Only ADHD was discussed as attention deficit with hyperactivity is seen more commonly in practice, than without hyperactivity (NIH Consensus Statement, 1998). The precise clinical presentation of the ADHD child can vary but what is constant in all cases is the presence of learning disorders that can influence children at any cognitive level (Berkow et al. 1992).

1.2 PROBLEM STATEMENT

The aim of this double blind controlled study was to evaluate the relative efficacy of Advanced Brain Food® and a Homoeopathic Complex (Quietude®) in the management of Attention Deficit Hyperactivity Disorder (ADHD) in males between the ages of 8 and 13 years, by means of an ADHD Rating Scale (Appendix F), Student Behaviour Log (Appendix I), and a Children's Checking Task (Appendix J1-J5).

1.3 OBJECTIVES OF THE STUDY

1.3.1 The first objective

The first objective was to determine the effectiveness of a nutritional supplement (Advanced Brain Food®) and a Homoeopathic Complex (Quietude®) in the management of ADHD signs and symptoms in terms of an ADHD Rating Scale (Appendix F).

1.3.2 The second objective

The second objective was to determine the effectiveness of a nutritional supplement (Advanced Brain Food®) and a Homoeopathic Complex (Quietude®) in the management of ADHD signs and symptoms in terms of a Student Behaviour Log (Appendix I).

1.3.3 The third objective

The third objective was to determine the effectiveness of a nutritional supplement (Advanced Brain Food®) and a Homoeopathic Complex (Quietude®) in the management of ADHD signs and symptoms in terms of a Children's Checking Task (Appendix J1-J5).

1.4 STATEMENT OF HYPOTHESES

1.4.1 The first hypothesis

It was hypothesised that a nutritional supplement (Advanced Brain Food®) would have no beneficial effect in the management of ADHD signs and symptoms in terms of the ADHD Rating Scale (refer Appendix F), the Student Behaviour Log (refer Appendix I) and the Children's Checking Task (refer Appendix K1-K5).

1.4.2 The second hypothesis

It was hypothesised that a Homoeopathic Complex (Quietude®) would have no beneficial effect in the management of ADHD signs and symptoms in terms of the ADHD Rating Scale (refer Appendix G), the Student Behaviour Log (refer Appendix J) and the Children's Checking Task (refer Appendix K1-K5).

1.3.3 The third hypothesis

It was hypothesised that there would be no difference in effect between the two groups in the management of ADHD.

CHAPTER 2

REVIEW OF THE RELATED LITERATURE

2.1 AETIOLOGY

ADD/ADHD is one of the most commonly diagnosed disorders of childhood development (Kendall and Hammen, 1995; Venter, 1996). It is believed to affect between 3 and 5% of all children of school age and although it also affects adults and adolescents, the figures here are not available (DSM-IV, 1994). The values for females are often under reported due to the fact that they go undiagnosed as their symptoms are attributed to emotional problems common in young girls (Kendall and Hammen, 1995; Berkow et al. 1992) and they are less aggressive and active than boys, which makes them less noticeable (Picton, 1997).

The diverse and conflicting opinions about ADHD have resulted in confusion for families, care providers, educators and policy makers (NIH Consensus Statement, 1998). The controversy raises questions concerning the literal existence of this disorder, whether it can be reliably diagnosed and, if treated, what interventions are most effective (NIH Consensus Statement, 1998; American Psychiatric Association, 1994).

ADD/ADHD is characterised predominantly by developmental inappropriate inattention and/or impulsivity and/or hyperactivity (Woods and Ploof, 1997).

Children with ADD/ADHD usually have functional impairment across multiple settings including their home, school and peer relationships (NIH Consensus Statement, 1998; Breggin, 2003).

The symptoms characteristic of this disorder namely hyperactivity, short attention span and impulsiveness are thought to suggest central nervous system involvement (Castellanos et al. 1996; DSM-V, 1994).

Diagnosis is a problem as it has been shown that many children are not identified or otherwise falsely identified by their paediatrician or doctor for a number of reasons (Breggin, 2003; Richardson, Hamley and Sassone, 2000). Testing of children is often limited and not comprehensive enough, case histories may not be detailed enough and often the influence of a teacher or school is enough to encourage a doctor to prescribe stimulant medication (NIH Consensus Statement, 1998; Picton, 1997; Oltmanns and Emerly, 1995). The most commonly used diagnostic method is from the Diagnostic and Statistical Manual – IV (1994).

Attention Deficit Hyperactivity Disorder is a heterogeneous behavioural disorder with multiple possible aetiologies. These may be classified into the following causations:

- environmental factors,
- central nervous system (CNS) insult,
- genetic origins and,
- neurochemical/neuroanatomical factors (Goldman, 1998).

2.2 PATHOGENISIS

The cause of ADHD is unknown but numerous factors have been identified which may play a role in the pathogenesis of this syndrome (Karen et al. 1997).

As a result of this undetermined aetiology, there is as yet no clear-cut method of determining when this disorder is present (NIH Consensus Statement, 1998). Scientific evidence suggests that the disorder is genetically transmitted in many cases and results from a chemical imbalance or deficiency of certain neurotransmitters, which are chemicals that help the brain regulate behaviour (Castellanos, 2000; Zametkin et al. 1990).

It has been proffered that ADD/ADHD is of neurological origin, and is caused by an imbalance of the biochemical neurotransmitters: dopamine, serotonin, and nor-epinephrine at the nucleus accumbens, locus coeruleus and prefrontal cortex (Burgess et al. 2000). It is also reported that other causes such as insult or slow maturation of the central nervous system, heavy metal poisoning, thyroid abnormalities and artificial additives in food may result in ADD/ADHD (Castellanos, 2000; Schoenthaler, 1986).

One specific cause for ADHD in humans has not been found (Karen et al. 1997). However, many theories have been put forth over the last century (World Health Organization, 1999; Holford, 2001). Following is a brief outline of the aetiological theories on the origin of ADHD.

2.2.1 Neuroatomic

The brain consists of modules specialised for processing specific data. These modules are autonomous to a degree in both function and neural representation (Frei et al. 2001). The outermost layer of the brain represents the cerebral cortex.

The cortical (frontal) section of the brain is related to learning and thinking. The layer underneath, the sub-cortex, comprises a relay system that is involved in sending messages to the processing and memory parts of the brain (Rapoport, 1995) This sub-cortical system consists of the brain stem's reticular activating system, thalamus, hypothalamus and basal ganglia (Guyton, 1989; Rapoport, 1995).

Laufer et al. (1957), who proposed that the symptoms of ADHD were caused by "diencephalic dysfunction," reported the first anatomical-based hypothesis for the cause of hyper-kinesis.

Recent research suggests that ADHD children generally have impaired functioning in the cortical and subcortical areas (Hynd et al. 1993). In particular, frontal lobe and prefrontal lobe dysfunction have been suggested (Hynd et al. 1991).

Anatomic neuro-imaging studies are converging in revealing differences in children with ADHD, compared to age-matched controls (Castellanos, 2000; Greenhill et al. 2002). ADHD children notably have a smaller brain volume (4% decrease from normal), as well as a smaller caudate nucleus, globus pallidus, anterior frontal cortex and sub-region of the cerebellar vermis (Castellanos, 2000). These volumetric differences appear early and are not secondary to stimulant medication.

In the early 1990s, many functional imaging techniques were used in a variety of clinical settings to image the brains of ADHD patients in comparison to normal control subjects. Swanson et al. (1998) integrated the findings across multiple studies and calculated the standardised effective size. It was found that there is a consistent moderate reduction of about 10% of the size in healthy controls in the frontal lobes (dorsolateral prefrontal cortex and anterior cingulate), basal ganglia (caudate nucleus and globus pallidus), and some regions of the corpus callosum (rostrum and splenium), which link frontal and parietal brain regions (Swanson et al. 1998; Castellanos, 2000).

A recent study done by the National Institute of Mental Health found that three structures in the right brain-prefrontal cortex, caudate nucleus and globus pallidus were affected by ADHD (Castellanos, 2000). These areas were smaller than those of children without ADHD, thus ADHD is thought to be rooted in an inability to inhibit thoughts.

Furthermore, ADHD children exhibit smaller frontal lobes and less activity in the striatum, which is a major dopamine-rich supply for the frontal lobes (Castellanos, 2000). The majority of ADHD children exhibit decreased perfusion in the pre-frontal cortex with intellectual stress (Amen et al. 1997).

Brain scans have identified a clear-cut chemical abnormality in people with attention deficit-hyperactivity disorder, a problem that makes life difficult for an estimated 3 to 5% of US school children scientists say (New York Times Syndicate - December 16, 1999).

With the development of imaging and isotope scanning techniques, studies of anatomy and glucose metabolism of ADHD children have been made possible (Swanson et al. 1998).

Positron emission tomography (PET) scan studies have shown reduced brain glucose utilisation, particularly as related to the right frontal lobe, in ADHD children (Zametkin and Rapoport, 1987). Furthermore, ADHD children show decreased blood flow in the frontal lobes (Hynd et al. 1993). In a recent study, it was shown that the rate at which the brain uses glucose, its main energy source, is lower in subjects with ADHD than in subjects without ADHD (Zametkin et al. 1990).

Analysis of electroencephalograms (EEGS) of boys with ADHD has found increased slow-wave activity in the frontal regions (Hynd et al. 1991). Although this research suggests frontal lobe dysfunction, some researchers believe the neurological basis for ADHD should not be limited to frontal immaturity or abnormality (Baizier, 2001). They believe ADHD is related to more widespread dysfunction in the brain (Benson, 1991). These results suggest that ADHD may have an organic basis and that dysfunction can be localised to cortical and striatal regions in the brain (Woods and Ploof, 1997; Castellanos 2000).

2.2.2 Neurochemical

Neurochemical hypotheses are based on the effects of neurotransmitters (Zametkin et al. 1990). These are chemicals that relay messages from one neuron to another through synapses (Castellanos, 2000). The neurotransmitters that function within the attentional

system are the catecholamines, which function in the neural circuits that control motivation and motor behaviours, including activity level, restlessness, and responsivity (Ballard et al. 1997). The neurochemical theories postulate that behaviours seen in ADHD are due to a dysfunction in the neurotransmitter system. Supporting this theory is the beneficial effect that certain medications, which have a direct effect on the neurotransmitters in the body, have on the disorder (Bazier, 2001).

ADHD is a neurobiological disorder with anatomic and functional impairments in the brain, leading to monoamine dysregulation and frontostriatal alterations in neural circuitry (Herscu, 1995). There is strong evidence that the catecholamines, dopamine and norepinephrine are important in the pathophysiology of ADHD (Castellanos, 2000). Dysfunction of dopaminergic and noradrenergic systems are constantly implicated in ADHD (Baizier, 2001; Holford, 2001). Dopamine and norepinephrine are important neuromechanisms governing focused attention (Castellanos, 2002).

2.2.2.1 Dopamine Theory

Dopamine is a neurotransmitter in the catecholamine family that functions in the brain. This hypothesis is based on an animal model of hyperactivity, on biochemical and on clinical pharmacological studies with ADHD subjects (Castellanos, 2000; Smalley et al. 2000; Zametkin and Rapoport, 1987).

Some evidence suggests there is a reduction in cerebral turnover of dopamine and decreased dopamine activity (dopaminergic dysfunction) within the brain of an ADD and hyperactive subject (Smalley et al. 2000).

The models of dopaminergic dysfunction cannot account for the findings that dopamine agonists have not proven efficacious when compared to stimulant treatments, nor have dopamine-blocking agents been deleterious (Zametkin and Rapoport, 1987). More recent studies reveal that hyperactivity and possible poor motor impulse control, in ADHD may result from excess dopaminergic activity in the striatum and/or nucleus accumbens (Castellanos et al. 1996).

According to Harvard Medical School, current research strongly suggests that ADHD is caused in part by a deficiency of norepinephrine in the ascending reticular activating system, and is thought that stimulant medications, such as Ritalin®, increase the levels of norepinephrine in that part of the brain, as well as probably increasing dopamine levels in the frontal lobes (Breggin, 2000; Rapoport, 1995).

Recent reports suggest that DNA variants of the dopamine D4 receptor gene are associated with the personality trait of Attention Deficit Hyperactivity Disorder (Paterson, 1999).

Boys with a low dopamine D4 receptor gene concentration exhibit significantly more symptoms of ADD/ADHD than boys with normal dopamine D4 receptor genes (Castellanos, 2000).

Many dopamine agonists that stimulate postsynaptic dopamine receptors have been given to patients and were ineffective. The models of dopaminergic dysfunction cannot account for the findings that dopamine agonists have not proved efficacious when

compared to stimulant treatments, nor have dopamine blocking agents been deleterious, unless other hypotheses are put forth (Zametkin and Rapoport, 1987).

2.2.2.2 Serotonergic Theory

Although serotonin has been studied less thoroughly in the neurobiology of ADHD, its role in the pathophysiology of this disorder has recently become an area of intense investigation. Considerable evidence suggests a role for this neurotransmitter in the aetiology of behavioural disorders characterisz~~z~~ed by dis-~~-~~inhibition including alcohol abuse, suicide, bulimia, antisocial personality disorder, conduct disorder and aggression (Castellanos, 2000). As ADHD is a behavioural disorder largely characterisz~~z~~ed by deficits in inhibition and is a well-known precursor for many adult disorders of impulse control, a role for 5-Hydroxytryptothan (5-HT) in ADHD has been hypothesisz~~z~~ed. Indeed, there is mounting evidence from both human and animal studies that serotonergic neurotransmission is necessary for mediating several of the behaviours present in ADHD (Schoenthaler et al. 1999).

A recent study of a mouse model of ADHD provided evidence which -linkedi~~ng~~ serotonin to the control of hyperactive behaviour (Gainetdinov et al. 1999).

All of the studies done have used L-tryptophan, the amino acid precursor to serotonin, and Fenfluramine®, an appetite suppressant that acutely increases and then depletes brain serotonin (Zametkin and Rapoport, 1987). No significant behavioural changes were seen in any of the ADHD patients tested, decreasing the likelihood of the veracity~~truth~~ of this hypothesis.

In conclusion, there is accumulating neurobiological evidence pointing towards thea role of the serotonin system in ADHD. The strongest support from existing data suggests that serotonin is responsible, at least in part, for mediating the hyperactive and impulsive components of ADHD behaviour (Hanna, Ornitz and Hariharan, 1996; Leary, 1994).

2.2.2.3 Noradrenergic Theory

Norepinephrine is another neurotransmitter in the catecholamine family. Kornetsky first proposed this hypothesis in 1970, stating that amphetamine may act as an inhibitor of either norepinephrine synthesis or turnover, or it may block the release of norepinephrine in the over aroused organism.

This was hypothesiszed in response to the observations that amphetamine, a sympathomimetic amine, causes a release of norepinephrine and most likely and increase in the rate of turnover. Therefore, ADHD could result from an increase in norepinephrine and amphetamine that may competitively bind to postsynaptic norepinephrine receptors, reducing noradrenergic neuro-transmission (McGough and McCracken, 2000).

Since then, studies have shown that some drugs, proven effective for ADHD, actually alter noradrenergic turnover and may argue for a pathological hyper-functioning of the noradrenergic system in ADHD subjects. Animal studies have shown the opposite effects. These studies lead to the hypothesis that animal hyperactivity is caused by norepinephrine depletion (Zametkin and Rapoport, 1987).

2.2.2.4 Non-specific Catecholamine Theory

Each of the specific neurotransmitter hypotheses above have led to either inconclusive or disproving results (World Health Organization, 1999). Therefore, since the stimulants used to treat ADHD affect multiple transmitters, it was thought that perhaps a dysfunction in the catecholamine neurotransmitters as a group was to blame (Amen et al. 1997; Castellanos et al. 1996).

A series of studies were performed using a group of drugs that also affect multiple neurotransmitters. They all had immediate and positive behavioural effects on children with ADHD (Castellanos, 2000). However, the close relationship between the transmitter systems affected and the fact that so many were affected does not illustrate that one was more important that any of the others. Clearly, though, the array of effective agents has served to put to rest any single neurotransmitter hypothesis (Castellanos, 2000; Zametkin and Rapoport, 1987).

2.2.2.5 The Hypoarousal Theory

Alertness and directed attention depends on the normal functioning of the reticular activating system (RAS) in the brain stem. Incoming sensory stimuli are filtered and sorted before neural impulses are "despatched" to the cerebral cortex. Stimuli not relevant to immediate functioning are at this point blocked from conscious awareness (Holford, 2001).

It has been postulated that children with ADHD are continuously in a state of hypo-arousal and are therefore unable to filter out irrelevant and distracting sensory input from

their external surroundings (Hanna, Ornitz and Hariharan, 1996). Research has shown that ADHD children have significantly less alpha activity on electroencephalogram (EEG) readings as compared to normal peers (Castellanos et al. 1996; Zametkin et al. 1990).

2.2.3 Genetics

Goodman and Poillion (1991) have indicated that the majority of causes of ADHD are attributable to organic problems. Their research indicated that genetics is the only presumed cause of ADHD; cited by 48% of the authors they investigated. However, no specific gene responsible for ADHD has as yet been isolated. There is some evidence that ADHD-type behaviours tend to recur in families, especially in first- and second-degree relatives of ADHD children (Barkley et al. 1990).

In a recent study, 55% of families presenting with an ADHD child has at least one parent with a lifetime diagnosis of ADHD. The frequency of ADHD in at least one parent was higher in families with at least one affected girl than in families with only affected boys (Faraone, Biederman and Monuteaux, 2000; Smalley et al. 2000).

The gender difference in prevalence of ADHD is consistent in a model of inheritance in which girls require a greater loading of family influences to develop ADHD (Zametkin, 1995). The lack of familial clustering of ADHD suggests that hyperactive and inattentive symptoms reflect common familial underpinnings and not unique familial effects (Smalley et al. 2000). A molecular genetic study suggests a possible relation to the D4 receptor gene (Levy, 1997).

Increasing evidence suggests that ADHD is an inherited condition. If one identical twin has symptoms of ADHD, the other twin has a 75-91% chance of sharing the same trait (Swanson, Lerner and Williams, 1995). Children who have ADHD are likely to have one close relative who also has ADHD. One-third of all fathers who had ADHD when they were young have children who have ADHD (Swanson, Lerner and Williams, 1995).

Adoption studies provide evidence of a genetic link to ADHD: biological children of parents with ADHD have a far higher chance of having ADHD than adoptive children of parents with ADHD (Cantwell, 1996; Levy, 1997).

The parents of children with ADHD show an increased incidence of hyperkinesis, sociopathy, alcoholism and hysteria. Monozygous twins are more alike than dizygous twins of same sex in measures of hyperactivity and inattention. Concordance for ADHD has been found to be much lower for half siblings than for full siblings, whether they are brought up by their mothers or are fostered (Kaplan and Sadock, 1988; Leary, 1994). These findings indicate that there may be a genetic link to ADHD.

2.2.4 Congenital Factors

Retrospective accounts suggest numerous congenital factors may be related to ADHD. However, there is no compelling evidence for specificity of perinatal or congenital factors (Cantwell and Hanna, 1989).

Maternal substance abuse during pregnancy may be associated with ADHD (Engel et al, 1992). Substances such as cocaine and nicotine may induce ADHD-related symptoms (Holford, 2000).

2.2.5 Familial Factors

These are very difficult to separate from genetic factors but the concept of parent and child temperament may be important (Tannock, 1998). Several studies suggest that interaction between parents and children may lead to an exacerbation of predisposed attention deficit behaviour (Safer and Malever, 1995).

Hyperactivity and poor impulse control can also occur in response to significant familial stress. Children who have experienced a divorce, a move, and a change in school or other significant life events may display impulsive behaviour, forgetfulness and absentmindedness, which may be mis-diagnosed as ADHD (Holford, 2001; Safer and Malever, 1995).

2.2.6 Parental Behaviour

Parents of ADHD children have often been shown to be unresponsive to the child's demands. The child's hyperactivity may merely be an attempt to elicit a response from the parent (Biederman, 1996).

2.2.7 Temperament

Children who have been active from birth are likely to remain so. The child's temperament and personality play an important part in the development of this ADHD (Biederman, 1996; Graham, 1986).

2.2.8 Central nervous system injury

2.2.8.1 Head Injury

One of the first theories was that minor head injuries or undetectable damage to the brain (due to early infection or birth complications) caused all attention disorders and learning disabilities. There has been no substantial evidence for this theory and thus it was dismissed (Tannock, 1998).

Subtle brain damage may be found in some children that may result from circulatory, toxic, metabolic, or other disorders during critical periods of prenatal development. In the early years of life, trauma, fever or inflammation can also cause subtle central nervous system (CNS) damage. These stresses may cause a range of disorders such as cerebral palsy, seizure disorder, and mental retardation (Woods and Ploof, 1997). The less severe forms of damage may produce a variety of learning disabilities including ADHD (Kaplan and Sadock, 1988; Tannock, 1998).

2.2.8.2 Environmental risk factors

While ADHD behaviours may be precipitated by deleterious social factors, with the exception of head injury occurring at a young age, there is no evidence of a single environmental agent causing ADHD (Paterson, 1999).

2.2.9 Diet

Feingold advocated foods containing additives, colourants and salicylates as the cause of ADHD in children (Feingold, 1973).

Although his diet has gained widespread popularity and offered an accessible alternative to ADHD management, numerous controlled studies have not yet validated his theory (Leary, 1994; Walker, 1983; Mattes and Gittelman, 1981).

Dietary supplements have been studied extensively over the last decade to understand the efficacy of dietary supplements for improving the symptoms of ADHD. A number of these studies have found strong positive correlation between the use of certain supplements and ADHD (Schoenthaler, 2000). In 1982, a conference was held to discuss the theory of what effect a restricted diet can have on the symptoms of ADHD. The data showed that the restricted diet only helped five percent of children with ADHD, and these were mostly young children or those with food allergies (Schoenthaler, 2000).

2.2.9.1 Refined Sugar and Food Additives

A later theory on the causes of ADD or ADHD suggested refined sugar and food additives attributed to making children hyperactive and inattentive (Holford, 2001).

This theory however was dismissed after it was found that there was no statistical validity for such a claim (Schoenthaler, 2000).

2.2.9.2 Colourants and Flavourings

The Lancet published a study in 1985, which reported that 79% ~~percent~~ of hyperactive children improved when certain foods were eliminated from their diets, only to become worse again when the foods were reintroduced. Artificial colourings and flavourings were the most serious culprits; sugar was also found to have a noticeable effect.

Additives included:	Artificial flavours and colourants
Preservatives included:	Butylated Hydroxyanisole (BHA) and Butylated Hydroxytoluene (BHT).
Sugars included:	Sucrose, Fructose, Corn syrup, Mannitol, Sorbitol and other Sweeteners.

An experimental study done in New York confirmed that during a ~~4~~four-year period, after eliminating food additives and colourants from the diet, there was a marked increase in academic performance in ADHD children (Schoenthaler et al. 1986).

2.2.10 Minerals

Vitamin and mineral deficiencies have been implicated in mental performance (Muller, 1995). Mineral status among those with ADHD has been the subject of several published clinical trials. ADHD children are deficient in certain minerals (Holford, 2000).

These deficiencies can affect both behaviour and school performance. The effect of vitamin and mineral supplements on academic performance and children's behavioural problems is well documented and although it currently seems unlikely that ADHD is caused solely by nutrient deficiencies, addressing such deficiencies can significantly improve ADHD symptoms (Holford, 2002; Muller, 1995).

2.2.10.1 Magnesium Deficient Diets

Magnesium deficiency is the most common of the mineral deficiencies associated with ADHD (Starobrat-Hermelin, 1998). In one study, magnesium deficiency was identified in 95% of ADHD children examined (Kozielec, 1997). The conclusion from the investigations is that magnesium deficiency occurs more frequently in children with ADHD than in healthy children. Analysis of the material indicated a correlation between increasing levels of magnesium and freedom from distractibility (Schoenthaler et al. 1998).

2.2.10.2 Iron Deficiency

Iron plays a role in the regulation of dopaminergic activity (Schoenthaler and Bier, 2000). The frequent occurrence of 'restless leg syndrome' in children with ADHD may be associated with iron deficiencies (Sever et al. 1997). Some studies have shown a clear relationship between low iron status and ADHD symptoms (Benton, Haller and Fordy, 1995).

2.2.10.3 Zinc

Zinc is required for the conversion of essential fatty acids (EFA~~'~~s) to prostaglandins (Black, 1998). In a recent study it was shown that zinc supplementation reduced the incidence of symptoms ~~that~~ with which ADHD children might present ~~with~~ (Stevens et al. 1995).

2.2.11 Vitamin Status

The Vitamin B-complexes includes all of the known essential water-soluble vitamins (except for vitamin C), including thiamine (vitamin B1), riboflavin (vitamin B2), niacin (vitamin B3), pantothenic acid (vitamin B5), pyridoxine (vitamin B6), biotin, folic acid and the cobalamins (vitamin B12). For the management of ADHD symptoms, the B-vitamins work together in the brain for the production of the various neurotransmitters, including dopamine, serotonin, 5-Hydroxytryptophan (5-HTP) and norepinephrine (Holford, 2001).

2.2.11.1 Vitamin B3 (Niacin/Nicotinamide)

Vitamin B3 is part of the vitamin B complex, which is considered by many to be the single most important set of factors needed for the body's proper maintenance of the nervous system, proper functioning of cells and energy metabolism (Holford, 2002).

Niacin deficiency or imbalance plays a role in the symptoms of mood disorders. Observational and experimental studies have shown an association between niacin and aggression, anxiety, ADHD, bipolar disorder and depression (Strohle, 2003).

Clinical research has demonstrated that vitamin B3 supplementation may help to reduce peripheral breakdown of L-Tryptophan. As a result, L-Tryptophan will not be used up for niacin production in the peripheral parts of the body, thus allowing it to be transported into the central nervous system where it can be converted to serotonin (Holford, 2002). It subsequently leads to an increased production of serotonin, a deficiency of which might lead to ADHD (Chouinard et al. 1999).

2.2.11.2 Vitamin B5 (Pantothenic Acid)

Pantothenic acid is responsible for helping to synthesize a neuro-chemical called Co-enzyme A (CoA) which combines with choline in the brain to produce the neurotransmitter Acetylcholine (Castellanos, 2000). Although supplementation with pantothenic acid has not been proven as a treatment option for attention deficit disorder, it most definitely affects production of the neurotransmitter acetylcholine that may play a role in the development of ADD/ADHD (Holford, 2001).

In a recent clinical study involving older adults with cerebral disorders researchers found evidence that increasing levels of choline by way of supplementation helped to improve memory and cognitive function (Fioravanti et al. 2004).

2.2.11.3 Vitamin B6 (Pyridoxine)

The main function of pyridoxine is to convert amino acids into serotonin. It forms an integral part in the metabolic pathway for the manufacture of brain chemicals, and an imbalance that can cause symptoms such as depression and ADHD (Holford, 2001).

Vitamin B6 is an important coenzyme for the biosynthesis of neurotransmitters. These neurotransmitters are required for optimal brain functioning. Researchers in Spain observed a clinical improvement in behaviour and school performance when patients were supplemented with vitamin B6 and folic acid (Fioravanti et al. 2004).

2.2.11.4 Vitamin B12

Vitamin B12 is essential for normal nervous system function and red blood cell production. Scientists at Baylor University Medical Centre reported that vitamin B12 and folic acid deficiencies could alter neurotransmitter function and contribute to neurologic and psychiatric pathologies (Fioravanti et al. 2004). Holford (2002) demonstrated that Vitamin B12 accelerates the learning process and is important for the health of the brain cells.

2.2.11.5 Folic Acid

Folic acid has a protective function in the brain. It protects the brain from chemicals like food additives and preservative~~s~~ additives (Holford, 2002).

2.2.12 Amino Acids

Assays of amino acid metabolism have generally revealed imbalances of these essential nutrients in ADHD. Serum amino acid levels as well as other nutrient cofactors may influence synthesis pathways for certain inhibitory and excitatory neurotransmitters (Kolesnichenko et al. 1999).

Research in the area of amino acids and ADHD points to a defect in metabolism ~~of~~/and synthesis of neurotransmitters. Simply loading the amino acid precursors to neurotransmitters appears to be of limited clinical effect, perhaps owing to the failure of such therapies to address the underlying errors of metabolism involved (Kolesnichenko et al. 1999).

2.2.13 Essential Fatty Acids (EFA~~'~~s)

A deficiency in EFA~~'~~s is being singled out by some as a cause of ADHD. EFA~~'~~s influence ADHD primarily in two ways: they influence gut permeability and are needed for the proper development of brain tissue (Burgess et al. 2000).

It is important to remember that a simple deficiency of EFA~~'~~s due to decreased/insufficient intake is unlikely (Holford, 2003). Studies have shown that in many cases the child diagnosed with ADD/ADHD has siblings who are not affected, yet they adhere to the same basic diet (Middleborough, 2001). There are three postulated reasons given for this deficiency:

a) ADD/ADHD children could have an inherent intestinal problem which leads to difficulty with absorption of EFA~~'~~s. A large-scale survey by the New York Institute for Childhood Development found that these children may be incapable of absorbing carbohydrates normally~~;~~, therefore a problem with fat absorption would not be unlikely (Medical Hypothesis, 1981).
b) ADD/ADHD children could have a metabolic requirement for higher levels of EFA~~'~~s than normal due to a genetic difference (Medical Hypothesis, 1981;

Graham, 1993). Researchers have shown that boys have a higher requirement for Gamma-linolenic acid (GLA), which coincides with a higher rate of ADD/ADHD in boys than girls (Richardson, 2000).

c) ADD/ADHD children may have a defect in their metabolism of EFA~~'~~s. This is substantiated by the fact that most EFA in our diets comes in the form of cis-linoleic acid. This is then converted by enzymes into GLA ~~Gamma-linolenic acid~~ and then into dihomolinolenic acid (DGLA) before it is converted into Prostaglandin E1 (PGE1), which is the usable form (Galli and Simopoulos, 1989). The initial step of this sequence is catalysed by the hormone delta-6-desaturase, which is most susceptible to blockade. This enzyme only matures after birth and therefore may lead to different rates of maturation in children (Medical Hypothesis, 1981; Graham J, 1993).

Delta -6-desaturase is blocked by a number of factors including:

- Trans-fatty acids which are commonly found, amongst others, in junk foods and margarine.
- Deficiencies of zinc, magnesium and pyridoxine (vitamin B6) which are necessary for the conversion of cis-linoleic acid to gamma linoleic acid (GLA).

2.2.14 Dysbiosis

The presence of dysbiotic flora is encouraged by the use of antibiotics that can destroy "friendly" or probiotic flora normally inhabiting the intestinal mucosa.

The average child undergoes multiple courses of antibiotic treatment in the first five years of life, typically without replacement probiotics (Holford, 2001). The resulting overgrowth of yeast and other pathogenic flora has been linked to alternation of immune function, food sensitivities and ADHD (Schoenthaler et al. 1998). A study reported that high levels of anti-metabolites, consistent with candida related complex, were identified in the urine of children with ADHD (Hanna et al. 1996).

2.3 CLINICAL PICTURE

The onset of ADHD typically occurs before the age of three with evidence often being present from birth (Berkow et al. 1992), and peak presentation with health care professionals occurs between the ages of seven and ten years (NIH Consensus Statement, 1998).

Children with ADHD do not show any signs of gross neurological deficit, but have some degree of hyperactivity, inattentiveness, distractibility and impulsivity in common. This is often accompanied by clumsiness and specific learning problems (Leary, 1994).

Symptoms of inattention affects classroom work and academic performance. Impulsive symptoms may also lead to the breaking of familial, interpersonal, and educational rules, especially in adolescence (American Psychiatric Association, 1991).

Children with this disorder are easily distracted and have frequent outbursts of bad behaviour, the inappropriateness of which they themselves may be unaware of, or they frequently blame others. Their actions appear disorganised, non-goal directed, and lack reflection on cause and effect (Reichenburg-Ullman, 1996).

They fail to give close attention to detail, their work tends to be messy and they often make careless mistakes in schoolwork and other tasks. ADHD individuals have great difficulty sustaining attention in tasks often shifting from one incomplete activity to another (Berkow et al. 1992).

They are easily distracted by irrelevant stimuli and frequently interrupt ongoing tasks to attend to trivial noises and events that are usually, and easily, ignored by others (American Psychiatric Association, 1991).

Impulsivity manifests as impatience, difficulty in delaying responses, frequently interrupting or intruding on others and making comments out of turn. They may grab things from others and touch things they are not supposed to. This picture often results in ADHD children being regarded as the "classroom clown." They engage in reckless activities with little consideration of possible consequences (American Psychiatric Association, 1991). They can exhibit overreaction to stress, have low frustration tolerance with catastrophic reactions of rage and outbursts, which subject them to continuous censure and rejection overtly or covertly (Breggin, 2001; Smith, 1983).

Hyperkinesis may be manifested by fidgetiness or squirming in one's seat, by excessive running or climbing in situations where it is inappropriate, or by talking excessively.

ADHD symptoms vary greatly with the individual's age and needs to be cautiously diagnosed, especially in toddlers and preschoolers, in whom symptoms can be variable and inconsistent (American Psychiatric Association, 1991).

Mood swings are common (Swanson, Lerner and Williams, 1995) and it is estimated that up to 25% ~~percent~~ of ADHD children suffer from depression (Berkow et al. 1992). Wong (1985) found that 40% ~~percent~~ of children with learning disabilities scored in the depressed range on the Roberts Apperception Test for Children.

A study conducted in Los Angeles County over a three-~~-~~year period found that 50% ~~percent~~ of the children under the age of fifteen who committed suicide had been identified as having a learning disability, as compared to five to eight percent in the general population (American Psychiatric Association, 1994; Peck, 1985).

2.4 DIAGNOSIS OF ADHD

Attention-deficit hyperactivity disorder (ADHD) is a common, heterogeneous disorder, conservatively estimated to affect three to five percent ~~3% to 5%~~ of school-age children (American Psychiatric Association, 1994; Anderson et al. 1987; Shaffer et al. 1996).

Attention Deficit Disorder (ADD) or Attention Deficit Hyperactivity Disorder (ADHD) is a collection of symptoms or criteria, rather than a true diagnostic entity (Borak, 2002). There are no laboratory tests or specific features that have been established as diagnostic in the clinical assessment of ADHD (American Psychiatric Association, 1991).

Although ADHD is more prevalent in boys than in girls, little doubt exists that it is also an important cause of psychiatric disability in girls. While the exact prevalence of the disorder in females remains unclear it may not be minor (American Psychiatric Association, 1991).

ADHD is a common psychiatric disorder that significantly hampers psychosocial adaptation (Biederman, 1996; Tannock, 1998).

Precise guidelines and criteria for the clinical diagnosis of ADHD in children are not universally accepted (Reichenburg-Ullman, 1996); this may account for the large variances in ADHD statistics in different countries. In a trainee survey on residents at seven Ohio paediatric programmes it was found that 30% ~~percent~~ of children evaluated for ADHD were not given that diagnosis (the majority were considered to have behavioural problems due to family dysfunction (Stancin et al. 1990). Further confusing the picture is that the concern the child raises in a social environment also varies according to family expectations and societal attitudes (NIH Consensus Statement, 1998).

Health care providers, such as paediatricians or child psychologists can diagnose ADHD with the help of standard guidelines from the American Academy of Paediatrics (DSM – IV-TR, 2000). The diagnosis involves gathering information from several sources, including school, caregivers and parents. The health care provider will consider how a child's behaviour compares with that of other children the same age.

The primary ADHD signs are behavioural and an accurate diagnosis is best made by an experienced health care professional. Medical histories, school reports, rating scales, and checklists are essential for diagnosis (Mathews, 2000).

Due to the lack of specific organic signs in ADHD, if a diagnosis is made, it remains a clinical one (NIH Consensus Statement, 1998).

2.4.1 Examination

2.4.1.1 History

On questioning, parents of ADHD children commonly report excessive motor activity when the children were toddlers. Clinical examination of children and young people presenting with ADHD should include a systems inquiry, details of previous health problems, current drug treatment and physical examination (Achenbach, 1996).

ADHD is associated with several co-morbid conditions, including Tourette's syndrome, a history of abuse or neglect, lead poisoning, previous encephalitis, drug exposure in utero, low birth weight and mental retardation (Breggin, 2002).

There may be a history of child abuse or neglect, multiple foster placements, neurotoxin exposure, infections and drug exposure (American Psychiatric Association, 1991). These conditions can mimic or contribute to the symptoms of ADHD (Breggin, 2000).

In addition, sharing a family history can offer important clues about your child's condition (Breggin, 2003).

For an accurate diagnosis, a paediatrician will need to obtain information about the child directly from the child's classroom teacher or another school professional. A child's teacher may write a report or discuss the following with the paediatrician:

- The child's behaviour in the classroom
- The child's learning patterns
- How long the symptoms have been a problem

- How the symptoms are affecting the child's progress at school
- Ways the classroom programme is being adapted to help the child
- Whether other conditions may be affecting the symptoms (Berkow et al. 1992).

2.4.1.2 Parent/Guardian Interview

The interview with the parent(s) or guardian(s) of the child or young person with ADHD is the foundation of assessment (Dulcan, 1997). The purpose is to obtain information relating to the child's behaviour in order to make an informed diagnosis and to formulate a treatment plan (Dulcan, 1997).

Parents/guardians should be asked details of the history of the child's current problems, the nature of the symptoms (frequency, duration, situational variation) and any associated behaviours. Emphasis should be on diagnostic criteria for ADHD and associated disorders which might include the following:

- Information about performance in the school/nursery setting, including details of academic achievement as well as social functioning in relation to other children and staff, should be reviewed and permission sought to contact the school.
- The clinician should determine what treatment (if any) the child/young person has received in the past.
- Some enquiry as to the impact of dietary factors may be considered, although there is insufficient data to support routine dietary assessment of individuals (Sanger et al. 1992).

- Parental reports of current child psychopathology have been shown to provide an accurate means of assessment (NIH Consensus Statement, 1998).

2.4.1.3 Physical Signs

Minor physical anomalies such as hypertelorism (developmental defect characterised by an abnormally wide space between two organs or parts) (Glanze, 1986; Rapoport, 1995), highly arched palate and low set ears, may occur at a higher rate than in the general population (American Psychiatric Association, 1991). Waldrop and Goering (1971) found an increased incidence of head circumference out of the normal range in ADHD children. Also noted were higher rates of epicanthus (vertical fold of skin from upper eyelid), widely spaced eyes, curved fifth finger, absence of ear lobes and widened spaces between the first and second toes.

2.4.1.4 Laboratory Signs

There are no proven tests for ADHD at this time. Many theories have been presented. Studies however, have shown that the following tests have little value in diagnosing an individual child:

- Screening for high lead levels in the blood
- Screening for thyroid problems
- Computerised continuous performance tests
- Brain imaging studies such as CAT scans, MRI's, etc.
- Electroencephalogram (EEG) or brain wave test (Berkow et al. 1992).

2.4.1.5 Soft Neurological Signs

On examination EEG abnormalities may be detected while neuropsychological testing sometimes shows non-localis~~z~~ed soft neurological signs (minor neurological abnormalities) and frontal lobe dysfunction (Sierles, 1993). Neurological soft signs (NSS) may be defined as minor abnormalities in the neurological examination in the absence of other features of fixed or transient neurological disorders (American Psychiatric Association, 1991).

Wender (1971) found an incidence of 50% ~~percent~~ of children suffering from ADHD to exhibit soft neurological signs such as-

- Visual perception impairment
- Auditory perceptual impairment
- Poor motor co-ordination
- Mild reflex asymmetries
- Poor balance
- Clumsiness
- Strabismus
- Mild choreoform movements.

Neurological signs and minor physical anomalies cannot independently exclude or confirm a diagnosis of ADHD (NIH Consensus Statement, 1998).

2.4.1.6 Diagnostic and Statistical Manual of Mental Disorders Criteria

The DSM-IV classification has grouped two main symptom categories, firstly inattention and secondly hyperactivity/impulsiveness. In each of the categories, six of the nine listed traits must be present for at least six months to warrant a diagnosis of ADHD.

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

Inattention

a) often fails to give close attention to details or makes 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 schoolwork, chores, or duties in the workplace (not due to oppositional behaviour or failure to understand instructions)
e) often has difficulty organis~~z~~ing tasks and activities
f) often avoids, dislikes, or is reluctant to engage in tasks that require sustained mental effort (such as schoolwork or homework)
g) often loses things necessary for tasks or activities (e.g. toys, school assignments, pencils, books or tools)

A)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 squirms in seat

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 (adolescents or adults, may be limited to subjective feelings of restlessness)

d) often has difficulty playing or engaging in leisure activities quietly and is often "on the go"

~~d)~~e) often acts as if "driven by a motor"

~~e)~~f)often talks excessively

Impulsivity

~~f)~~g)often blurts out answers before questions have been completed

~~g)~~h) often has difficulty awaiting turn

~~h)~~i)often interrupts or intrudes on others (e.g. butts into conversations or games)

C~~B~~) Some hyperactive-impulsive or inattentive symptoms that caused impairment were present before age 7 years.

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

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

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

Because the criteria require symptoms to be present for at least six months in multiple settings, diagnosis of ADHD is not possible at a clinical visit, yet medical doctors promote the idea of office diagnosis (Patricelli, 1994). Because of the unreliability and subjectivity of measurement tools, no single objective measure can diagnose ADHD (McBurnett, Lahey and Pfiffner, 1993). Assessment should include a network of parents and professionals using multiple methods in multiple situations, along with a thorough review of school records (Hunt, 1988; McKinney, Montague and Hocutt, 1993).

Assessment instruments should be used to detect learning disabilities and emotional-behavioural disorders, which can co-occur with ADHD (McKinney, Montague and Hocutt, 1993). Likewise, testing must include sensitivity to other DSM-IV disorders which may co-occur with ADHD, preclude a diagnosis of ADHD, or which need to be considered as alternative explanations before a diagnosis of ADHD is made (DSM-IV).

2.4.1.7 Assessment Scales for ADHD Diagnosis

There are a number of assessment scales used to diagnose ADHD and measure the effectiveness of ADHD therapies such as the Conner's/CADS Scale, the Swanson, Kotkin, Atkins, M-Flynn, and Pelham (SKAMP) scale, and Clinical Global Impression (CGI-I) scales.

2.4.1.7.1 Conner's/CADS Scale

Various Conner Rating Scales Revised (CRS-R) versions offer flexible administration options while also providing the ability to collect varying perspectives on a child's behaviour from parents, teachers, caregivers and the child or adolescent (NIH Consensus Statement, 1998).

There are three versions—parent, teacher and adolescent self-report—all of which also have a short and long form available. In addition, there are three screening tools that offer the option of administering a 12-item ADHD Index or the 18-item DSM-IV Symptom Checklist or both. These instruments also offer versions for parents, teachers, and adolescents.

Two formats are included for self-report ratings and observer ratings. Both the self-report and observer forms provide multimodal assessments of the same behaviours and problems and contain an identical set of scales, sub-scales and indexes. Conner's Abbreviated Assessment Rating Scale (CAARS) forms are available in long, short, and screening versions.

Long Version

The long version of the self-report form (CONNER'S ABBREVIATED ASSESMENT RATING SCALE SELF REPORT [CAARS-S: R]) and observer form (CONNER'S ABBREVIATED ASSESMENT RATING SCALE: OBSERVER LONG VERSION [CAARS-O: L]) has 66 items and contains nine empirically derived scales that help assess a broad range of problem behaviours:

- Inattention/Memory Problems
- Impulsivity/Emotional Liability
- Hyperactivity/Restlessness
- Problems with Self-Concept.

The long forms also include:

- **DSM-IV® ADHD symptom measures** - help assess Inattentive Symptoms, Hyperactive-Impulsive Symptoms and total ADHD Symptoms
- **ADHD Index** - 12 items that help identify respondents who may benefit from a more detailed clinical assessment
- **Inconsistency Index** - helps identify random or careless responding

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Short Versions

The short versions of the Conner'~~o~~s abbreviated assessment scale self-report form (CAARS-S: S) and observer form (CAARS-O: S) contain abbreviated versions of the

factor-derived subscales that appear on the long forms, plus the ADHD Index and the Inconsistency Index (Pelham and Hoza, 1996).

2.4.1.7.2 SKAMP Scale

The Swanson, Kotkin, Atkins, M-Flynn, and Pelham (SKAMP) scale measures the classroom manifestations of ADHD by assessing attention and deportment on a 7-point scale (American Psychiatric Association, 1991).

SKAMP is an important treatment evaluation for ADHD because it can help assess the pharmacodynamic profile of an ADHD subject and intervention in a classroom setting. SKAMP generates scores on two~~2~~ behavioural sub-scales, namely "Attention" and "Deportment" (behaviour). These subscales are derived from direct observations of subject behaviour during class periods.

2.4.1.7.3 Clinical Global Impression Scale (CGI Scale)

Investigators use this scale in a clinical setting. The CGI-I is scored on a 7-point scale, with a positive response to therapy defined as a score of either (1) "very much improved" or (2) "much improved" at endpoint. ~~-~~Those patients with higher numerical ratings are considered therapy non-responders; e.g., a rating of (4) indicates that the condition was unchanged and a rating of (7) that the condition was very much worse.

Clinicians are instructed to report their "best estimate" of the patient's level of functioning based on the closest match to the descriptions offered for each rating increment (American Psychiatric Association, 1991).

2.4.1.7.4 ADHD Rating Scale-IV

The ADHD Rating Scale – IV was developed by G. J. DuPaul, T. J. Power, A. D. Anastopoulos and R. Reid in 1998. It was developed for use by clinicians and doctors in research as well as in~~with regards to~~ individual patient assessment.

There are at present many different behaviour based questionnaires in use for the assessment of ADD/ADHD~~.~~, U~~u~~nfortunately very few of these are directed at the DSM-IV criteria which are the standard set for diagnosis of this disorder. The questions asked in the questionnaire are adaptations of the DSM-IV criteria with the difference being that the questions omit the word "*often*"~~.~~. ~~i~~Instead, respondents are asked to indicate the frequency with which each symptom is noted. By alternating the questions regarding the two components of the disorder, the developers aimed to reduce response bias (DuPaul et al. 1998).

It is furthermore based on the DSM –IV criteria for ADD/ADHD with questions targeting both the inattention and hyperactivity/impulsivity aspects. Every odd question is aimed at the inattention aspect and every even question is aimed at the hyperactivity/impulsivity. The responses used reflect the frequency of the behaviour so that a question can be answered as being never, rarely, sometimes, often, or very often. Due to the distinction between the two different components of the disorder, the scale can be used to assess improvement in either one of these areas or as a total score. Each component consists of nine symptoms each. The final scores can also be compared to the normative data for children of similar age groups based on studies in the United States of America (DuPaul et al. 1998; Middleborough, 2001).

2.4.1.7.5 Student Behaviour Log (SBL)

This questionnaire (Appendix I) was developed by David Lazear according to Howard Gardner's guidelines to the eight different behaviours in man (Gardner, 1998). It has since been adapted to examine all aspects of a child's concentration abilities and interaction with peer groups (Lazear, 1999). This questionnaire examines the following aspects of a subject: Verbal-linguistic, Logical-mathematical, Visual spatial, Bodily-kinaesthetic, Musical-rhythmical, Interpersonal, Intrapersonal and naturalist behaviours (Armstrong, 1999). All the above-mentioned behaviours are areas where a child with ADHD might have difficulty ~~with~~ (Gardner, 1998; Armstrong 1999; Cambell et al. 1999). This scale has been shown to be sensitive to drug treatment and parent training in behaviour management (Lazear, 1999). Although this assessment technique examines a certain amount of bodily kinaesthetic behaviour (hyperactivity), it is also concerned with basic concentration and behavioural capabilities of a child. It is a useful assessment technique for parents/teachers that have an ADHD child (Lazear, 1999).

The Student Behaviour Log (SBL) can also be scored for the hyperactivity index, which comprises of six items (the mean score often being used to select children for research purposes).

Table A

Factors and items for the Student Behaviour Log

Factor	Items
Conduct Problems	2, 5, 10, 11, 17, 20, 26
Inattention	6, 7, 8, 9, 15
Psychosomatic problems	3, 4, 24
Impulsivity/ hyperactivity	1, 12, 13, 14
Anxiety	16, 18, 21, 23
Hyperactivity index	19, 22, 25, 27, 28, 29

Each item is rated “uncertain”, “does not fit at all," "fits slightly, "fits moderately" or "fits strongly", with 0, 1, 2, 3 or 4 points assigned to each answer respectively.

The mean of the scores for each factor is calculated by summing the points across all items comprising that factor and dividing by the number of items in that factor. A mean score of 1,5 in each factor is regarded as the lower limit for establishing hyperactivity (Gardner, 1998, Lazear, 1999).

2.4.1.7.6 Vigilance Testing

Concentration problems may be due to a simple attentional disturbance, or to inability to maintain a purposeful attentional focus or, as is often the case, a combination of both. Vigilance testing examines the ability to sustain attention for a length of time.

The variations to this testing technique are limitless. They typically involve sequential presentation of stimuli over an extended period of time. The subject is instructed to indicate in some way when a given number or letter is perceived (U.S Department of Health and Human Services, 2002).

2.4.1.7.7 Children's Checking Task (CCT)

This cancellation test is a valuable assessment of motor-visual skills and especially of sustained attention (Strauss, 2000). The basic format consists of rows of letters, diagrams, or numbers. The patient is instructed to cross out a target letter, diagram or number. The performance is scored for errors and for time of completion. If there is a time limit, scoring is for errors and number of targets crossed out in the allocated time. These vigilance tests are performed easily by persons whose capacity for sustained attention is intact (Strauss, 2000). Thus, even one or two lapses on these tests may reflect an attention problem (Lezak, 1983).

The CCT (Appendices J2-J5) consists of four pages of vigilance tasks. Each page consists of a block with the target letter, number, symbol, or word at the top of the main block (consisting of random items). The first three pages consists of two blocks each, one with a single target and the other with two targets. Each block is arranged into three rows with 56 items per row. The single target blocks contain ten matches per row (30 matches per block) to be identified. The two-target blocks contain 48 matches per block. The fourth page consists of five columns of 45 three-letter words, a total of 225 words. The target word is at the top of the block, with 40 matches to be found. The pages consist of letters, numbers, symbols, and words respectively.

There are no flawless measures of ADHD, therefore multiple measures provide the most accurate assessment tool (Strauss, 2001). These should include parent ratings, peer ratings and direct observations (Gresham, 1981; NIH Consensus Statement, 1998).

2.5 DIFFERENTIAL DIAGNOSIS

Attentional difficulties and excessive motor activity are non-specific responses of the organism that can commonly be seen in completely unrelated disorders (Breggin, 2000). The most common cause of these two symptoms in children can be anxiety or depression (Kaplan and Sadock, 1988; Tannock, 1998).

Attention Deficit Hyperactivity Disorder (ADHD), sometimes inaccurately referred to as ADD (there is no clinical term by this name) is a disorder usually first diagnosed in infancy, childhood or adolescence (American Psychiatric Association, 1994; Holford, 2001; NIH Consensus Statement, 1998).

There are four~~4~~ recogni~~s~~z~~z~~ed types of ADHD. They are:

I. Predominantly Inattentive type;

II. Predominantly Hyperactive-Impulsive type;

III. Combined type (inattention and hyperactivity-impulsivity); and

IV. ADHD - Not Otherwise Specified.

There is a high level of correlation between children with ADHD and other psychiatric illnesses. This includes illnesses ranging from behavioural, mood, family, anxiety,

cognitive, social to school functioning, with the greatest increase in those with the ADHD combined subtype (Fletcher, 1999).

ADHD needs to be distinguished from other learning disabilities such as environmentally based underachievement (e.g., children with anxiety, phobias, depression or other psychiatric functional disorders) and mental retardation with uniform and broad deficiency in academic performance (American Psychiatric Association, 1991). When an impulsive, inattentive and hyperactive child also exhibits considerable aggressive and antisocial behaviour, differentiation between conduct disorder and ADHD may be difficult (NIH Consensus Statement, 1998).

Following is a brief outline of possible differential diagnoseis's (Biederman, 1991):

Epidemiology: Associated Conditions

A. Language and Learning Disability (10-15%)

   Usually less hyperactive and more inattention

B. Tourette's Syndrome (70% with tics have ADHD)
C. Oppositional Defiant Disorder (33% of ADHD patients)
D. Conduct Disorder(25-50% of ADHD patients)
E. Major Depression (20% of ADHD patients)
F. Anxiety Disorder(25% of ADHD patients)

II Psychiatric Conditions

A. Low self esteem
B. Major Depression
C. Anxiety Disorder
D. Conduct Disorder
E. Oppositional Defiant Disorder
F. Obsessive Compulsive Disorder
G. Poor Social skills
H. Substance Abuse

Consider if symptom onset in adolescence

III. Medications

A. Anticonvulsants
B. Antihistamines
C. Decongestants
D. Beta agonists

IV. General Medical Conditions

A. Hypothyroidism
B. Severe Anaemia
C. Lead Poisoning
D. Chronic illness

E. Hearing Impairment or vision Impairment

V. Neurological Conditions

A. Sleep disorders

B. Tourette's Syndrome

C. Seizure disorder (Petit mal)

D. Other learning disabilities

E. Language disorders

F. Mental retardation

1. Fragile X Syndrome
2. Foetal Alcohol Syndrome
3. Phenylketonuria

Vi. Environmental

A. Unsafe or disruptive learning environment

B. School curriculum not well matched to child's ability

C. Family dysfunction or poor parenting

D. Child Abuse or neglect

E. Parental Psychopathology

High Intelligence Quotient (IQ) and children with high intelligence (placed in academically under-stimulating environments. Children may complete tasks too quickly and cause disruptions in the class environment on completion of their own task). ADHD

should not be diagnosed if presenting symptoms are better accounted for by other mental disorders such as:

- Mood disorder
- Anxiety disorder
- Dissociative disorder
- Personality disorder
- Personality change due to general medication
- Substance related disorders
- Oppositional behaviour (American Psychiatric Association, 1991)

A misdiagnosis can easily be made in cases of suspected ADHD. This has practical consequences because treatment with psychostimulants is contraindicated in most of the above-mentioned disorders (Bazier, 2001, Breggin, 1999Kaplan and Sadock, 1985).

Webb and Latimer (1993) discuss another condition which can complicate ADHD diagnosis: Giftedness. Traits of gifted children which may lead to false ADHD diagnosis include off task behaviour, less need for sleep, questioning of rules and traditions, power struggles and resistance to repetitive tasks.

2.6 EVALUATION OF TREATMENT

Once a child has been diagnosed with ADHD, and the appropriate dose level for the prescribed drug has been identified, continued monitoring of response to treatment is essential. Several questionnaires used in the initial evaluation can be completed regularly by the parent and teacher of the ADHD child to establish the degree of change in

hyperactive behaviours (NIH Consensus Statement, 1998). In addition to this, the child on the medication should have a follow-up clinical examination every six to eight months. During this time height, weight, blood pressure, and heart rate should be recorded to determine potential side effects (Biederman, 1996).

2.7 MANAGEMENT

Current management of ADHD is multifactorial, often involving medication, behavioural counselling and dietary control. For some children behavioural modification and educational support is sufficient. Some children require only one form of therapy to improve while others respond with a combination of therapies. In some instances the parents of ADHD children can even attend parent counselling. This supports the theory that ADHD is multifactorial (Breggin, 2000; Holford, 2001).

Cerebral stimulants are the most widely used drugs for the management of ADHD. However, the results of several long-term follow-up studies have indicated minimal improvement beyond those obtained at the onset of treatment (Biederman, 1991; Breggin, 1998). It is still unclear whether stimulants do in fact improve long-term academic achievement (Breggin, 1999). Children with ADHD do not outgrow their problems. T~~;~~ ~~t~~herefore, long-term use of stimulants is often required~~needed~~, while ~~of which~~ the effects are limited in scope as well as ~~in~~ time (Whalen and Henker, 1991).

2.7.1 Behavioural Modification

Behaviour modification is a technique used to modify behavioural patterns in children with ADHD.

According to Green and Chee (1997), the basic law of behaviour modification states: "A behaviour which pays off for the child will be repeated - a behaviour that brings no advantage to the child will disappear."

This means that if the right behaviour is rewarded, it should happen more frequently, while ignoring what is undesired means it should disappear (Green and Chee 1997).

The key concepts of behaviour modification in the management of ADHD are immediacy and consistency in as many areas of the child's environment as possible (home, school and, if possible, during leisure activities) (Woods and Ploof, 1997). These concepts must be present in all forms of behaviour modification. As with other skills, consistency and immediacy need to be practiced and reinforced before they become automatic (Woods and Ploof, 1997). The secret of behaviour modification is reinforcement with small, frequent rewards (Green and Chee, 1997).

To encourage the best behaviour, hard, soft or cumulative rewards can be used. A hard reward is something tangible such as money, food or a special privilege. Soft rewards are praise, enthusiasm or a show of parental pride. Cumulative refers to the collection of stars, stamps or tokens, each given for a small period of good behaviour, and eventually adding up to a major prize (Green & Chee, 1997). As the child learns acceptable behaviour, so the rewards should be gradually decreased (Warner-Rogers, 1998). Parents and teachers need to initially give material rewards, along with praise, to reinforce appropriate behaviour and subsequently they may use praise alone to maintain the behaviour (Green and Chee, 1997; Warner-Rogers, 1998). Therefore rewarding positive

behaviours not only reinforces that behaviour but also provides the child with desperately needed success, which in turn builds their self-esteem (Green and Chee, 1997).

The basic strategies for parenting a child with ADHD include:

a) providing a high degree of positive attention and consequently no complaining about bad behaviour
b) developing clear, concise and consistent expectations for behaviour; and
c) utilis~~z~~ing non-physical negative consequences for problem behaviours in a non-punitive fashion (Warner-Rogers, 1998).

A disorganis~~z~~ed, unstable home environment can promote the development of symptoms more readily than one that is more structured and stable (Green and Chee, 1997). If the parents can learn to become more organis~~z~~ed and structured at home, the child with mild symptoms may make gains without medication. The need for structure is substantially more important in the ADHD child who likes to have a fixed framework to direct their day. They wake at a certain time, put their pyjamas under their pillow, straighten the duvet, get dressed, have breakfast, etc. If their equilibrium is thrown by anything different their ADHD symptoms may worsen (Green and Chee, 1997). Parents need to understand that the lack of a structured front within the home will only exacerbate the child's difficulties due, for example, to the obvious failure to provide needed consistency (Green & Chee, 1997; Woods and Ploof, 1997).

An important aspect of behaviour modification is in communication. Parents and teachers are advised to be very direct and explicit in communicating directions and

feedback. They should make eye-to-eye contact, use a clear, distinct voice and use simple terms. This is often the only way to maintain the child's attention while relating significant information (Green and Chee, 1997; Woods and Ploof, 1997).

Parents and teachers are advised to exaggerate the level of praise for the child's behaviour even in academic tasks (Green and Chee, 1997; Woods and Ploof, 1997). This is accomplished through the use of exaggerated facial expressions, gestures and an emotional tone of voice. The benefits of an exaggerated praise approach are twofold. First, it might help to activate the reinforcement systems of the brain. Secondly, ADHD children have an almost constant need for personal attention because of the failure of their own reward and punishment systems, leaving them with an intense awareness of an internal emptiness that can only be relieved through the overt expression of feeling from others (Green and Chee, 1997; Woods and Ploof, 1997).

2.7.2 Psychosocial Treatments

Ness and Price (1990) believe that "the best non-medical interventions (for ADHD) are practical, common sense adjustments to an impulsive and disorganised style." They also go on to state that those suffering from ADHD will be more frustrated, apathetic and pessimistic than others about psychosocial treatments, decreasing the probability of success.

Thus, the important first step in the treatment of a person with a learning disability is the ~~gaining~~acquisition of their participation, and helping them to becoming active participants in their treatment. Two of the first obstacles that must be overcame initially

in order to do this are the common feelings of denial and under-confidence (Ness and Price, 1990).

According to Barton and Fuhrman (1994), the four problems that are brought into the therapeutic setting by the ADHD client are stress and anxiety resulting from struggles to meet life's demands, low self-esteem, and feelings of incompetence, grief over lack of accomplishments and helplessness. Another factor that can be added here is social skills.

Up to 20% of children and adults with ADHD will not respond to medications, and many more will experience only partial remission of their symptoms. Additionally, a significant portion of the impairment from ADHD comes from~~or~~ its secondary impact on self-esteem and social skills deficits. These are the targets of psychotherapeutic interventions (Clinical Practice Guideline, 2001).

2.7.3 Occupational Therapy

Another intervention that forms part of the multidisciplinary approach to ADHD is the work of occupational therapy. The occupational therapist works on the child's sensorimotor skills through the use of tactile, kinaesthetic, motor planning and motor accuracy skills as well as verbal and visual cues (Kleinman and Stalcup, 1991). This may include such simple skills as tying shoelaces, throwing a ball straight, catching a ball or moving smoothly (Green and Chee, 1997). Their visual perception is targeted through the use of figure-ground discrimination, parts-to-whole-relationships and spatial relationships. Their cognitive skills are enhanced with sequencing skills, number concepts and measuring skills (Kleinman and Stalcup, 1991).

Many ADHD children have problems with handwriting and it is the occupational therapist that helps with their pencil grip, organisation of letters and the flow from word to word (Green and Chee, 1997).

Occupational therapists work with children with Sensory Integration Dysfunction. They use sensory integration and recreational activities to build up their basic sensory and motor skills (Kranowitz, 1998).

2.7.4 Orthodox Pharmaceutical Intervention

Since medication is frequently used in the treatment of ADHD, it is important to have reasonable expectations regarding its effectiveness and to be aware of potential side effects.

2.7.4 (A) General Medication Information

- Each person responds uniquely to medication.
- Medications are very safe. More studies have been done ~~about~~ on children taking stimulant medications than any other medications, including non-prescription drugs. Medication should be prescribed in minimal doses.
- Individuals do not have a physical craving for medication. When medication is out of the blood stream, the individual goes back to exhibiting full-blown ADHD symptoms.
- Both hyperactive and non-hyperactive individuals can benefit from medications.
- Medication is effective for 54% of non-hyperactive children and 80 ~~to~~ 90% of hyperactive children.

- Medication does not cause psychosis but can precipitate a psychosis in susceptible individuals (NIH Consensus Statement, 1998).

2.7.4 (B) Medication Does Not:

- Teach the ADHD individual how to cope and compensate for difficulties.
- Imply a “magic pill".
- Just treat hyperactivity. Medication also helps with impulsivity and attention difficulties.
- Lead to aggressive, dangerous behaviour.
- Cause seizures or Tourette’s Syndrome (Karen et al. 1997; NIH Consensus Statement, 1998).

2.7.4 (C) Medication Does:

- Treat ADHD symptoms.
- Influence long-term progress and prognosis of ADHD children when utilis~~z~~ed in conjunction with treatment modalities specific for ADHD.
- Stimulate the attention centre of the brain to function more normally.
- Affect impulsivity, attention, and behaviour positively. More specifically, stimulants can increase attention span, concentration, and compliance; improve handwriting and fine motor skills and allow improved peer relationships. In addition, a decrease in impulsivity, aggressiveness, and hyperactivity can occur. (Karen et al. 1997).

2.7.4.1 Psychostimulants

Introduction

Many clinicians treating ADHD believe that greater harm "emotionally and socially" occurs to untreated ADHD patients than could possibly come from the side effects of the medications. Not everyone agrees, however, and many parents are concerned about the side-effects of medications. Nevertheless, the usefulness of psychostimulants in the treatment of ADHD has been established and is the standard of care in mainstream medicine (Greenhill et al. 2002).

Stimulants have been widely prescribed by physicians for more than 40 years for a variety of disorders including Parkinsonism, depression, fatigue states, narcolepsy, asthma, obesity and hyperactivity in children (Karen et al. 1997). They are widely prescribed as adjuncts to other remedial measures (psychological, educational and social) in ADHD management. Stimulants should only be prescribed for ADHD after remedial measures such as psychological and sociological intervention as well as appropriate educational placement have been proven to be insufficient alone (Borak, 2002).

There are many styles for the use of medication in ADHD. Some clinicians increase the medicine's dose until the desired effect is achieved or too many undesirable side effects (such as jitteriness, ~~stomach-aches~~stomach-aches or headaches) occur and do not subside after several weeks (Breggin, 1999; Holford, 2001).

Some clinicians use other medications to treat the side effects of the psychostimulants, an approach that becomes even more problematic for parents already concerned about the consequences or long-term effects of medication use (Karen et al. 1997).

Mechanism of Action

The exact mechanism by which psychostimulants benefit ADHD children has not yet been identified. They are known to facilitate dopamine and noradrenalin release by inhibiting the action of monoamine oxidase (MAO) (Leary, 1994; Lawson-Wending, 1981). The calming action is non-specific and has been reported in normal children as well (Karen et al. 1997; Spencer et al. 1996).

Beneficial Effects

Many controlled studies using both subjective and objective criteria to judge response, indicate that psychostimulants are beneficial in children with ADHD when used for one to three months (Caroll and Rounsaville, 1993; Swanson et al. 1995). When properly prescribed, stimulants have a paradoxical calming effect on hyperactive children, and will facilitate their educational and social development (Caroll and Rounsaville, 1993; Karen et al. 1997).

Stimulants have been shown to improve short-term learning by prolonging attention span; improving goal directed activity, concentration and classroom behaviour and reducing impulsiveness, hyperactivity, and aggressive behaviour in children. The behaviour of treated children was found to be organised in a more efficient and effective manner, with better processing of incoming stimuli and better planned responses (Frei et al. 2001;

Kaplan and Sadock, 1985; Karen et al. 1997). Benefits were particularly seen in ratings of behavioural functioning, lowered activity levels, and improved attending skills (Levin and Kleber, 1995).

Side Effects and Contraindications

Side effects commonly seen include decreased appetite, insomnia, increased heart rate or blood pressure, stomach- -aches (Holford, 2001), withdrawal symptoms and irritability (Swanson et al. 1991).

Long-term use of the psychostimulants may limit linear growth and weight, most likely due to appetite suppression, decreased food intake, and altered secretion of growth hormone (Holford, 2001; Wilens et al. 1997). Children with a history of tics, Tourette's disorder, thought disorder, or psychosis should not receive stimulants as they have been alleged to precipitate the symptoms of such disorders (Bazier, 2001; Breggin, 2000; Lowe, 1982). Loss of spontaneity and apathetic withdrawal are signs of ~~overdosage~~over-dosage (Leary, 1994).

Special Prescriber's Points

Occasional "drug holidays" over weekends and holidays restores sensitivity to the stimulants and allows the dosage to be decreased when therapy is reinstated (Caroll and Rounsaville, 1993; Swanson et al. 1995). As many as 20% ~~percent~~ of children who respond poorly to one stimulant are believed to show a positive response to a second one. It is generally recommended to begin stimulant medication with Ritalin®, followed by Cylert® if a poor response to Ritalin® develops (Karen et al. 1997).

Determining when it is safe to discontinue medication is a controversial topic. Barkley (1981) has found that as many as 26% ~~percent~~ of the children can discontinue the medication because of improved self-control after two years of treatment.

He does state that this is not because the children are cured or have outgrown their disorder, but because their problems are not severe enough to warrant the continued use of stimulants.

2.7.4.1.1 Methylphenidate HCL (Ritalin®) and sustained-release preparations (Ritalin-SR®, Concerta®, Metadate CD®):

Methylphenidate is said to affect as much as a 70% improvement in those affected with ADHD. Methylphenidate is supposed to induce hyper-perfusion [increase blood supply] to the frontal lobes of the brain (Greenhill et al. 2002). Of all the ADHD medications, Ritalin® is the most inconsistently absorbed (Caroll and Rounsaville, 1993). Some adults and children absorb as much as 80-90% of the medication, whereas others only absorb 30-40% of a medication dose (Karen et al. 1997). Since 1990, prescriptions for Ritalin have increased by 500% ~~percent~~ in the USA (Holford, 2001; Breggin, 1999; Baizer, 2001; Wilens et al. 1997). In South Africa there is considerable evidence that methylphenidate is being over prescribed (Cotton, 1988; Middleborough, 2001; Strauss, 2000).

Methylphenidate is derived from the same family as cocaine and increases blood flow to the basal ganglia and decreases flow to frontal and motoric regions (Bazier, 2001).

Cerebral studies in persons with ADHD have shown cerebral hypo-perfusion in the frontal lobe and decreased blood flow to the caudate nucleus (Zametkin and Rapoport, 1987).

Methylphenidate hydrochloride (Ritalin®), a piperidine derivative of amphetamine, is the drug of choice when it comes to stimulant treatment of ADHD children (Holford, 2002).

Mechanism of Action

The mode of action of methylphenidate hydrochloride in man is not completely understood, but methylphenidate presumably activates the brain stem arousal system and cortex to produce its stimulant effect (Castellanos, 2000).

There is neither specific evidence that clearly establishes the mechanism whereby methylphenidate produces its mental and behavioural effects in children, nor conclusive evidence regarding how these effects relate to the condition of the central nervous system (Spivak et al. 1999).

Methylphenidate hydrochloride in extended-release tablets is more slowly but as extensively absorbed as in the regular tablets (Karen et al. 1997). Bioavailability of the methylphenidate hydrochloride extended-release tablet was compared to a sustained-release reference product and an immediate-release product (Karen et al. 1997; MD Pharmaceutical Inc., 2002).

The extent of absorption for the three products was similar, and the rate of absorption of the two sustained-release products was not statistically different (Karen et al. 1997).

Methylphenidate is an indirectly acting sympathomimetic agent (a drug that stimulates the sympathetic nervous system) that releases dopamine and noradrenalin inhibits MAO and probably acts directly on catecholamine and serotonin receptors (Spivak et al. 1999). As compared to the other amphetamines, Ritalin acts more directly on dopamine release (Strohle, 2003; Zametkin and Rapoport, 1987).

Beneficial Effects

In numerous comparative studies, Ritalin® proved to be statistically superior to dextroamphetamine (Dexedrine®) and magnesium pemoline (Cylert®) in several measurements of improvement. Behavioural improvement appeared to be sustained for at least two years as judged by subjective criteria (Baizer, 2001; Paterson, 1999; Spivak et al. 1999). Approximately 35% ~~percent~~ of children with ADHD show a dramatic improvement on Ritalin®, while another 35% ~~percent~~ show only moderate improvement (Safer and Allen, 1976; Zametkin, 1995). 25 ~~Twenty five to~~ 30% percent of children are poor responders and need alternative treatment (Leary, 1994; Berkow et al. 1992; Greenhill et al. 2002).

Methylphenidate has been reported to increase attentiveness, reduce distractibility, enhance concentration and decrease motor restlessness and hyperactivity in ADHD patients (Barkely et al. 1990; Paterson, 1999).

Methylphenidate is reliably associated with a short-term enhancement in sustained attention, impulse control and reduced activity levels (Levin and Kleber, 1995; Strohle, 2003). Positive behavioural effects include increased compliance, independent play and

responsiveness to social interactions with parents, teachers, and especially peers (Mino and Ohara, 1991; Whalen et al. 1991). However Buhrmester et al. (1992) found that stimulants had a general dampening effect on social behaviour, significantly reducing social engagement and increasing dysphoria [an emotional state characterised by depression, restlessness, and malaise] (Greenhill et al. 2002).

Side Effects and Contraindications

Undesirable side effects such as nervousness, sleep disturbances, appetite suppression, anxiety, high blood pressure and headaches are common (Holford, 2001; Karen et al. 1997). These side effects are largely dose dependant and spontaneously remit once the medication is discontinued (Karen et al. 1997; Levin and Kleber, 1995).

Prolonged therapy may result in anorexia, weight loss and growth retardation (South African Medicines Formulary, 1995). Decreased growth rates are only temporary. Once the medication is stopped the child catches up with his peers with no long-term growth problems (Kozielec, 1997). Less commonly seen side effects include dizziness, dyskinesia, rashes, nausea, abdominal pain, hypertension, hypotension, palpitation, tachycardia and ~~,~~ arrhythmias~~, and headache~~. (Holford, 2001; Breggin, 2000).

Other reactions induce hypersensitivity (including skin rash, urticaria, fever, arthralgia, exfoliative dermatitis, erythema multiforme with histopathological findings of necrotizing vasculitis, and thrombocytopenic purpura); anorexia, nausea, dizziness, palpitations, headache, dyskinesia; drowsiness, blood pressure and pulse changes, both up and down; tachycardia; angina; cardiac arrhythmia; abdominal pain; weight loss during prolonged

therapy (Holford, 2002). There have been rare reports of Tourette's syndrome (Baizer, 2001).

The drug has also been shown to inhibit certain drug metabolising liver enzymes, causing a prolongation of the half-life of certain anti-epileptic drugs, tricyclic antidepressants and MAO inhibitors (Karen et al. 1997). This may result in an elevation of therapeutic doses to toxic levels. Acute episodes of psychosis and hallucinations have been reported with Ritalin (Lambert and Hartsough, 1998; NIH Consensus Statement, 1998).

Methylphenidate is contraindicated in patients with marked anxiety, tension, thyrotoxicosis, tachyarrhythmias, agitation, or glaucoma. It should be used cautiously in epileptic and hypertensive patients (Bazier, 2001; Karen et al. 1997).

Drug Interactions

Methylphenidate may decrease the hypotensive effect of guanethidine. It should be used cautiously with pressor agents and MAO inhibitors. Human pharmacologic studies have shown that methylphenidate may inhibit the metabolism of coumarin anticoagulants, anticonvulsants (phenobarbital, phenytoin, primidone), phenylbutazone, and tricyclic anti-depressants (imipramine, clomipramnine, desipramine).

Downward dosage adjustments of these drugs may be required when given concomitantly with methylphenidate (Karen et al. 1997).

Special Prescriber's Points

Abuse and dependence on the amphetamine-type drugs (e.g., methylphenidate) are common (Clarke, 1986; Bazier, 2001). Although there have been no reports of psychic dependence with methylphenidate use in ADHD children, the possibility for drug abuse needs to be acknowledged (Barkley, DePaul and Conner~~ors~~, 1999; Biederman, 1996). A recent study showed that children with learning disabilities (including ADHD) display a higher proportion of chemically dependant traits when compared to children without any learning disabilities (Karacostas, 1993).

Kavale (1985) completed an extensive review of the research done on the efficacy of methylphenidate in ADHD management. He could not draw any conclusions on methylphenidate's benefit on ADHD. This was mostly due to methodological flaws in studies completed on methylphenidate's efficacy (NIH Consensus Statement, 1998).

Long-term follow-up studies indicate that children on methylphenidate may continue to have difficulty in school, exhibit behavioural disorders and have poor self-esteem into adolescence, which may persist as personality-trait disorders into adulthood (Bazier, 2001; Holford, 2001; Karacostas, 1993; Milman, 1979).

2.7.4.1.2 Pemoline (Cylert®):

Cylert® ranks third in sales for the treatment of ADHD (NIH Consensus Statement, 1998).

Unlike other stimulant medications, Cylert® has an onset of action of about an hour and must be taken for 1-2 weeks before improvement occurs. Cylert® is more expensive than Ritalin® or Dexedrine® (Bazier, 2001).

Important points about Cylert®:

- Liver enzyme changes have occasionally been noted in patients taking Cylert®. Baseline liver enzymes are recommended with follow-ups at three to six~~3-6~~ months.
- Persons using alcohol are at higher risk with this medication. Patients with either liver or kidney compromise should not take this medication.
- SSRI~~'~~s (Selective Serotonin Reuptake Inhibitors) affect the use of Cylert® due to their effects on the liver P450 isoenzymes.
- Cylert® is a useful alternative for patients with cardiovascular disease, as it has no effect on this system.
- Cylert® may cause insomnia, appetite suppression, and tics (American Academy of Paediatrics Committee on Children with Disabilities, 1996; Bazier, 2001).

Mechanism of Action

Cylert® (Pemoline) has a pharmacological activity similar to that of other known central nervous system stimulants, however, it has minimal sympathomimetic effects. Although studies indicate that Pemoline may act in animals through dopaminergic mechanisms, the exact mechanism and site of action of the drug in man is not known (Spivak et al. 1999).

There is ~~neither~~ also no specific evidence, which clearly establishes the mechanism whereby Cylert® produces its mental and behavioural effects in children, nor conclusive evidence regarding how these effects relate to the condition of the central nervous system (NIH Consensus Statement, 1998).

Pemoline (Cylert®) is metabolized by the liver. Cylert® is excreted primarily by the kidneys with approximately 50% excreted unchanged and only minor fractions present as metabolites (Spivak et al. 1999).

Cylert® (Pemoline) has a gradual onset of action. Using the recommended schedule of dosage titration, significant clinical benefit may not be evident until the third or fourth week of drug administration (Pelham et al. 2001).

Side Effects and Contraindications

Common adverse affects to Cylert® include insomnia, anorexia, and weight loss (weight gain occurs after three to six months of continued administration). Less frequently occurring side effects include dizziness, drowsiness, headache, depression, hallucinations, rashes, nausea and gastrointestinal distress (Karacostas, 1993; Pelham et al. 2001).

Most of these reactions were, however, reversible on withdrawal of the drug (Karacostas, 1993; Spivak et al. 1999). Hepatic dysfunction has occurred in a few patients with elevated hepatic enzyme levels. One case of fatal hepatic dysfunction has been reported (NIH Consensus Statement, 1998).

2.7.4.2 Second-line Therapy - When Stimulants Cannot Be Used

2.7.4.2.1 Antidepressant Medications

Anti-depressant medication is often prescribed for persons with ADHD who cannot tolerate or show no signs of improvement on stimulants, or for those who have mood sequealae (Karen et al. 1997). Dosage levels, while there are guidelines, are essentially determined on a case--to--case basis. Because ADHD persons are often poor self observers it may be helpful to enlist a person with whom the ADHD person is close in order to note any improvement or deterioration in behaviour following medication changes (Spivak et al. 1999).

It should be strongly emphasi~~z~~sed that treatment of ADHD with anti-depressants does not necessarily imply that the patient is depressed. Antidepressants are often used to enhance the control of the patient's symptoms, rather than as treatment of primary depression (Spivak et al. 1999).

Some clinicians feel that the SSRI's (Selective Serotonin Re-uptake Inhibitors) have superior benefits, especially with children, for the mooded aspects of ADHD because they cause less side-effects than older generation anti-depressants such as the tricyclics (Imipramine®, Nortriptyline®, Amitryptyline®, Desipramine®). Desipramine® has become less prescribed due to some unexplained sudden deaths which appeared to be related to heart conduction patterns (Bush et al. 1999).

2.7.4.2.2 Busiprone (BuSpar®) in Treating ADHD

Busiprone (BuSpar®) is a relatively new anti-anxiety medication which shows some promise in treating ADHD when psychostimulant medications are not effective or their side effects cannot be tolerated (Bush et al. 1999; Spivak et al. 1999). It can also "potentiate" benefits of the serotonergic antidepressants.

The ~~side effects~~side effects of Busiprone are often tolerated better than those of other medications used for ADHD (Pelham et al. 2001). It should always be remembered that, for reasons still not fully understood, every individual responds differently and uniquely to a specific medication. The effective administration of a specific medication for any psycho-neurological condition will still - and most likely ~~will~~ for quite some time - remain an art, rather than a science (Spivak et al. 1999).

2.7.4.2.3 Imipramine (Tofranil®)

Tofranil® is a tricyclic antidepressant that has a marked sedative action in children. Beneficial results however, have not been consistent (Pelham et al 2001). These drugs should only be considered as alternatives in patients who cannot tolerate or do not respond to Dexedrine®, methylphenidate, and Cylert® (Karen et al. 1999).

Mechanism of Action

This drug acts pharmacologically by blocking the re-uptake of noradrenaline and serotonin into the presynaptic neuron and indirectly modifies their rate of release. To some extent, it also inhibits dopamine re-uptake (McCracken, 1991).

Beneficial Effects

Tricyclic antidepressants have been shown to effectively increase attentiveness and reduce distractibility in children and adults.

Tofranil® has been identified as being superior to a placebo in inducing school return and in global therapeutic efficacy in 40~~ to~~ 85% ~~percent~~ of ADHD cases (Huessy and Wright, 1970 Karen et al. 1997; Waizer et al. 1974; Wiener, 1977; Winsberg, et al. 1972). It was found to decrease hyperactivity, aggression, defiance, and inattentiveness. In a comparative study between methylphenidate and Tofranil®, all rating measurements favoured Tofranil® (Karacostas and Fisher, 1993; Wiener, 1977). Other investigators have found that, although Tofranil® may initially control ADHD, thereafter the child's behaviour deteriorates over a two to three month period (Katz et al. 1975; Karen et al. 1997; Bazier, 2001).

Side Effects and Contraindications

The main side effects of Tofranil® include nausea, weight loss, insomnia, dry mouth, constipation, drowsiness, gastric upset and difficulty with micturition. Syncope and seizures may be precipitated (South African Medicines Formulary, 1995).

Special Prescriber's Points

Two to three weeks of therapy are required in order to see a therapeutic response to the tricyclic antidepressants (Wiener, 1977).

2.7.4.2.4 Fluoxetine(Lorien®;Lilly-Fluo~~e~~xetine®; Nuzak®; Prozak®)

Fluoxetine is one of a group of new generation antidepressants, which selectively inhibits serotonin re-uptake (Karen et al. 1997).

Mechanism of Action

It selectively blocks serotonin re-uptake at the pre-synaptic neurons.

Beneficial Effects

A positive response may only be seen after two to three weeks of continued therapy.

Side Effects and Contra Indications

Common side effects include headache and gastrointestinal disturbances. CNS effects include nervousness, drowsiness, and confusion. Fluoxetine should be used with caution in patients with hepatic or renal impairment and epilepsy (Pelham et al. 2001).

Special Prescriber's Points

Safe -use in children has not been established (South African Medicines Formulary, 1995).

2.7.5 COMPLEMENTARY/ALTERNATIVE TREATMENTS FOR ADHD

2.7.5.1 Biochemical Tissue Salts

William Schuessler, a German physician, identified 12~~twelve~~ different mineral salts in 1873 which are essential for human life. He postulated that the balance of these ~~twelve~~12 mineral salts were essential for building and maintaining health, and that they could also be used to treat disease (Boericke and Dewey, 1984).

The Schuessler system is based on 12~~twelve~~ remedies prepared according to the homoeopathic law to D6 potency (1:1 000 000) (Goodwin, 1980).

According to Schuessler's theory, symptoms presented by an ADHD child are indicators of various mineral deficiencies. Subsequently, administration of these minerals to the ADHD child should result in an improvement in his/her overall condition (Fisher, 1978).

A study conducted by Muller (1996) showed that mineral therapy was effective in decreasing the overall hyperactivity exhibited by an ADHD child. She advocates the use of mineral therapy as alternative to cerebral stimulants (such as Ritalin®) in some cases, or as a reinforcing treatment in others (Muller et al. 1996).

2.7.5.2 Homoeopathic Treatment

2.7.5.2.1 Introduction

Jouanny (1993) defines homoeopathy as a therapeutic method which clinically applies the law of similars, and which uses medicinal substances in weak or infinitesimal doses. This system consists of prescribing a weak dose of a substance to the patient, which when administered to a healthy person, causes symptoms similar to those exhibited by the ill patient.

Homoeopathy has been successful in treating ADHD and other childhood behaviour problems using individualised homoeopathic remedies (Johnston, 1996; Reichenburg-Ullman, 1996; Herscu, 1995; Rohrer, 1995). Individually chosen homoeopathic remedies have been estimated to have a success rate of at least 70% ~~percent~~ when used for one year (Reichenberg-Ullman, 1996). Original drug provings using homoeopathic remedies indicate that there are approximately 250 different remedies which may be effective in treating concentrational difficulties, when selected appropriately (Schroyens, 1993).

2.7.5.2.2 History

The founder of homoeopathy, Samuel Christian Hahnemann, qualified as a medical doctor in 1779. He practised medicine for a number of years (while supplementing his income as a translator) before becoming totally disillusioned with the conventional medical practices of his time. He eventually gave up being a doctor and worked as a translator (Lockie and Geddes, 1995).

In 1790, while translating a German text, he came across a passage about cinchona (Peruvian bark). The author stated that quinine (an alkaloid from cinchona) was a good treatment for malaria. Hahnemann investigated further by dosing himself with quinine and recording all his symptoms in detail. He found that he developed the symptoms of malaria despite the fact that he did not actually have the disease. This recurred every time he took a dose of quinine and disappeared as soon as he stopped taking it. Hahnemann experimented upon himself and those around him with every medicinal substance known in his time. Having determined their actions, he then tried these

substances out as therapeutic agents on ill patients who displayed symptoms similar to those induced in healthy people (Jouanny, 1993).

During his experimentation Hahnemann noticed that using material doses of medications resulted in various side effects.

He therefore gradually reduced the doses until the side effects subsided. As he increased the dilution, he introduced a method of shaking the substance (he believed that this released the energy of the remedy). He called this method of shaking "succusion" and dilution together with succusion "potentisation" (Borland, 1982).

Following six years of research Hahnemann concluded that he had discovered a new system of medicine in which a drug and a disease that produce similar symptoms cancel each other out (Lockie and Geddes, 1995).

2.7.5.2.3 The Law of Similars

The law of similars is the fundamental principle of homoeopathy. It was first observed by the Greek physician Hippocrates in the fifth century BC. It was only centuries later, in 1790, that Hahnemann studied this principle further (Lockie and Geddes, 1995).

"Similia Similibus Curantur - Like should be cured by like", is the summary of the homoeopathic principle of medicine. In essence, this homoeopathic law means that any substance capable of provoking certain symptoms in a healthy person is capable of curing similar symptoms in a sick person (Eizayaga, 1991).

2.7.5.2.4 The Laws of Cure

Dr Constantine Herring, an American homoeopath, further established homoeopathy in America during the 1820's. He devised the laws of cure, which are used in practice by carefully observing the patient's reaction to a medication. If the laws are being observed, the medication is moving towards healing the patient. As soon as symptoms start moving against the laws, the case and medication prescribed needs to be re-evaluated (Lockie and Geddes, 1995).

The laws of cure are:

i) Symptoms move from the top of the body downward

ii) Symptoms move from the inside out

iii) Symptoms move from the most important organs to the least important

iv) Symptoms disappear in the reverse order to their appearance

2.7.5.2.5 Potency

Potency is the term used to indicate the strength of the homoeopathic remedy. Potentisation is a process of serial dilution and succusion peculiar to homoeopathy. A combination of a number and letter indicates the potency of the remedy, the number indicating the number of successive dilutions that have been carried out, the letter refers to the proportion of the dilution. C (Centesimal) stands for a one in 99 dilution, while a D (Decimal) denotes a one in nine dilution (Lockie and Geddes, 1995).

For each stage of the dilution and succusion process, one part of the previous dilution is added to 99 parts of water or alcohol and this would result in a C potency (one in nine for a D potency). For example a D6 potency of selenium tells us that crude selenium was diluted one part in 9, followed by succusion, a total of six times, resulting in a dilution of one part in 60 000 (Hayfield, 1994).

According to ~~Avogardo's~~Avogadro's constant, once a remedy has been diluted beyond 12C (D24 or 1: $1x10^{24}$), it is highly unlikely that a molecule of the original substance remains in the dilution (Lockie and Geddes, 1995).

2.7.5.2.6 Aggravations

While experimenting, Hahnemann noticed that some of his patients were reporting that their symptoms worsened before becoming better. This initial aggravation of symptoms is a sign that the remedy is working and has prompted one's body into healing itself. Typical aggravations only last a few hours and healing should follow rapidly (Lockie and Geddes, 1995).

2.7.5.2.7 Homotoxicology

Homotoxicology is, in essence, an extension of the Hahnemannian theory of homoeopathy. The underlying concept is that all manifestations of life (e.g. disease and health) depend on the conversion of chemical compounds. Any toxic substance (termed a homotoxin) disturbs this equilibrium between healthy and diseased states. Therefore diseases are seen as the expression of the battle of the organism against toxins in its attempt to counteract and expel them (Bianchi, 1989). If the organism cannot expel these

toxins, it resorts to increased pathological means ~~are resorted~~ to make up for the damage already sustained. The final stage of this process is the neoplastic phase, or cancer.

The medication used in this clinical trial is an anti-homotoxic like medication consisting of six ingredients with varying potencies. The efficacy of these antihomotoxic preparations has been substantiated through scientific and clinical experimental investigation.

It has been claimed that these combination preparations are more effective than the individual application of their constituents (Heel®, 1989).

2.7.6 QUIETUDE®

2.7.6.1 Treatment Quietude®

Quietude® is a registered French Homoeopathic Remedy and is made in accordance with strict French Homoeopathic Pharmacopoeia standards (Boiron®-France, 2001). This product is safe and effective with no side effects. This product is non-habit forming and shows no drug interactions (Boiron®-France 2001).

Quietude® is administered in a syrup form at a dosage of 5ml twice daily. This homoeopathic complex consists of six~~6~~ different homoeopathic remedies combined in a syrup form. The syrup's main ingredient is 7.5% sucrose that has a minimal to no effect on blood sugar levels (Boiron®- France, 2001).

The main indications for this homeopathic complex are:

- Occasional nervousness.
- Inability to concentrate.
- Hyper-kinetic behaviour (Boiron®-France, 2001)

2.7.6.2 Manufacturer's Warning

It is recommended that one stop using Quietude® and consult a doctor if symptoms persist for more than two weeks. Insomnia may be a symptom of serious underlying illness. As with any drug, if pregnant or nursing a baby, ask a health professional before use (Package insert-Quietude®)

2.7.6.3 Indications of individual constituents and homoeopathic picture of Quietude®

A) Chamomilla vulgaris 9C (1.5g):

The main guiding symptoms of this remedy comes from the mental and emotional symptoms, where peevishness, restlessness are the chief indications. There is a whining restlessness present (Vermeulen, 1997). Impatient, irritability, whining and restless (Boericke, 1995). The child seeks a cause for being peevish at everything. He is cross and sleepless. There is melancholia, and constant moaning and muttering (Vermeulen, 1997). Tossing about during sleep. Nightly sleeplessness from anxiety and visions. Aggravations arise from complaints on falling asleep and awakening (Jouanny, 1997). He may present with the following: Anxiety, uneasiness, fretting and moaning at trifles,

irritable and impatient mood and , eomits words when not spoken to. There is often a great confusion in the head (Corson, 1992).

B) Gelsemium sempervirens 9C (1.5g):

The leading expression of Gelsemium is its low nervous condition, manifested by drowsiness, languor, disposition to be quiet, and erethism. Dullness, delirious of falling asleep, emotional excitement (Boericke, 1995). This remedy acts powerfully upon the motor nervous system, causing a passive congestion of the brain and spinal cord, and as a result giving rise to general prostration and paralysis of the whole muscular system, both voluntary and involuntary (Boericke, 1995).

The circulation is increased, the mental powers become sluggish, the mucous membranes are irritated and inflamed, the conditions resembling remittent and catarrhal types of fever are manifest (Boericke, 1995).

Characteristic symptoms:

Incapacity to think or fix the attention. Dullness of the mental faculties. Irritable, sensitive; desires to be let alone. Delirium in sleep; half waking, with incoherent talk (Boericke, 1995).

Cataleptic immobility, with dilated pupils, closed eyes, but conscious (Vermeulen, 1997).

C) Hyoscymus niger 9C (1.5g):

Lascivious mania, constant carphologia, deep stupor, mind wanders all the time, inability to concentrate on one activity. Mind wanders, cannot focus on one thing at a time (Boericke, 1995).

This remedy acts especially upon the cerebrospinal system, affecting particularly the sensorium and the muscular system, in the former producing perversion of the perceptive and intellectual faculties-illusions and hallucinations, and causing a distinct mania partaking of the quarrelsome or obscene character. Its cerebral manifestations partake more of a purely nervous excitability, and resemble more particularly the type of cerebral disorder occurring in typhoid conditions, typhus fever, and delirium tremens (Vermeulen, 1997).

On the muscular system, through the motor nerves, it acts with great power, producing paralysis, spasmodic affections of single parts and convulsions, but more especially paralysis of the involuntary system. The most essential feature of the drug is its increased sensorial activity and nervous excitement. When spoken to answers properly, but immediately stupor and delirium return (Vermeulen, 1997).

D) Kali Bromatum 9C (1.5g):

Potassium Bromide is a white crystalline salt that is used in photography. In orthodox medicine it was once used in large doses for severe epilepsy and other convulsive disorders (Lockie and Geddes, 1995). As a homoeopathic remedy, potassium bromide has

many other key uses as listed in the Materia Medicas, the most relevant of these, with relation to ADHD, include:

Profound melancholic delusion, must do something-move around. Brain fag, easily forgets what he was doing. Gets fidgety, active delirium (Boericke, 1995).

The physiological action of this drug is not fully determined, yet it is quite probable that its chief action is upon the nervous system, affecting most prominently those portions of the spinal cord, which receive and transmit reflex impulses, causing diminished reflex excitability of the nerve ~~centers~~centres (Corson, 1992).

It next acts upon the peripheral ends of the efferent nerves, causing paralysis, and finally affects the cerebrum, causing dilated pupils, intoxication, weakness of mind, hallucinations, etc. (Corson, 1992).

It thus causes primarily a depressed circulation in the cranium and throughout the body, lessening the blood supply, and thus causing, in connection with the action upon the nervous system, functional paralysis of nearly all the organs and tissues of the body (Corson, 1992).

The subsequent dilatation gives rise secondarily to congestion, exciting the depressed nerve ~~centers~~centres to a morbidly increased action, both sensory and motor, giving rise to hyperesthesia and convulsions, thus, according to Dr. Hale, becoming "homoeopathic" to all the morbid conditions and symptoms in which it has been found useful by the "allopathic school." (Corson, 1992).

E) Passiflora Incarnata 3X (1.5g):

This remedy has a quieting effect on the nervous system and i~~.~~ ~~I~~nability to concentrate (Boericke, 1995). Some of the key characteristic symptoms are:

Nervous excitement, and irritation with muscular twitching - evidences of approaching convulsions in childhood, ~~–~~ with marked cerebral fullness are indications, and it is given at any time preceding or during convulsive paroxysms if it can be swallowed. It is indicated in convulsions of any character (The American Materia Medica, Therapeutics and Pharmacognosy, 2001).

Passiflora has a depressant effect on central nervous system activity; it is used for it~~'~~s sedative and soothing properties, to lower blood pressure, prevent tachycardia and for insomnia. The alkaloids and flavonoids have both been reported to have sedative activity in animals. Many of the flavonoids, such as apigenin, are well-known for pharmacological activity, particularly anti-spasmodic and anti-inflammatory activities. It is the herb of choice for treating intransigent insomnia. It aids the transition into a restful sleep without any 'narcotic' hangover. It may be used wherever an anti-spasmodic is required, e.g. in Parkinson's disease, seizures and hysteria. It can be very effective in nerve pain such as neuralgia and the viral infection of nerves called shingles. It may be used in asthma where there is much spasmodic activity, especially when there is associated tension.

Ellingwood (1989) considered it specific for "wakefulness, disturbed sleep from mental worry, and exhaustion from cerebral fullness and from excitement, especially with feebleness."

Anaemic patients are relieved by it, also the wakefulness of infants and the aged. It is not usually efficient if the wakefulness is caused by pain, nor when the patient is in full strength. Nervous excitement, and irritation with muscular twitching, evidences of approaching convulsions in childhood, with marked cerebral fullness are indications, and it is given at any time preceding or during convulsive paroxysms if it can be swallowed. It is indicated in convulsions of any character.

F) Stramonium 9C (1.5g):

This plant is strongly narcotic and its main use in medicine has been as a pain reliever for rheumatism, neuralgia and sciatica (Lockie and Geddes, 1999). As a homoeopathic remedy, it has many other key uses as listed in the Materia Medica's, the most relevant of these, with relation to ADHD, include:-

Ceaseless talking, delirium, violent. Sees ghosts, hears voices. Brain fag, inability to concentrate (Boericke, 1995).

Acts chiefly upon the sensorium, increasing its activity, perverting its function, and giving rise to nausea, delirium, and to hallucinations. On other portions of the body Stramonium only acts through sympathetic irritation from the brain. In this manner it produces dilated pupils, diminished general sensibility, perversion of the special senses, convulsive motions, intense sexual excitement, suppressed urine, etc (Vermeulen, 1997).

Dullness of all the senses. Alternate exaltation and melancholy. Stupid indifference to everybody and everything (Boericke, 1995).

All above-mentioned remedies are in a syrup form and two~~2~~ measuring spoons are equal to 7.5g of sucrose (Boiron®-France, 2001).

2.7.6.4 Other Ingredients of Quietude®

Lactose, Sucrose, Magnesium sterate

2.7.6.5 Side Effects and Contra-indications

Homoeopathic preparations are known to have minimal to no side effects and do not result in dependency. There is no possibility of over-dosage as the remedies are repeatedly diluted to the extent that they have no direct toxic activity (Lockie and Geddes, 1995). They are safe to use over long periods of time (Reichenberg-Ullman and Ullman, 1996).

It is a fact that homoeopathic medicines have no side effects. The term 'side effects' when referring to ~~of~~ a medicine comes from modern pharmaceuticals. These drugs are aimed at one area of the body such as the cardiovascular system, the gut, the kidneys, etc. Though they have a primary area of action, they also affect other areas of the body. If these other effects are undesirable they are known as adverse side effects. Streptomycin, an excellent anti-tuberculosis agent, has been known to cause deafness. The deafness is an adverse side effect. Homoeopathic medicines are not employed against one particular

area or organ of the body but rather it matches the totality of symptoms that a patient might present with (Reichenberg-Ullman, 1996).

2.7.7 ADVANCED BRAIN FOOD®

Advanced Brain Food® is a registered nutritional supplement and is approved by the Medicines Control Council of South -Africa.

Bioharmony® S.A. is a reputable company and is involved in the manufacturing of amongst others Advanced Brain Food® (used in this clinical trial) and has an ISO9000 rating. Advanced Brain Food® is a nutritional supplement especially formulated with the main objective to correct nutritional deficiencies or neurological imbalances ~~that~~ with which a child with ADD/ADHD might present ~~with~~.

Advanced Brain Food® is a nutritional supplement formulated to meet the needs of children and adults with learning and behavioural difficulties. According to research done by Holford in the United Kingdom (1998), the individual nutrients in Advanced Brain Food® have been shown to enhance neurological function and learning capabilities as well as assisting in moderating blood sugar changes (Holford, 2000). This combination of nutrients offers the perfect solution in assuring that children receive the appropriate nutrients essential for growth (Holford, 2000).

Neurotransmitter imbalances might result in poor attention span, inability to concentrate and/or hyperactive behaviour.- Advanced Brain Food® is a unique blend of vitamins, amino acids and herbs, which provide ideal amounts of nutrients used by the brain to normalis~~z~~e imbalances in brain chemistry and neurotransmission, ~~that~~ which plays an

important role in maintaining short–term memory, concentration and hyperkinetic behaviour (Holford, 2001).

2.7.7.1 The Synergy effect

As with all nutrients, the effects of enhancing mental performance through supplementation of "smart nutrients" are likely to be far greater when taken in combination with other supplements rather than individually. Not only are results better, but smaller dosages of each are required to achieve results (Holford, 2002). For example, in a study by Bartus (1993), old laboratory rats with age related memory decline were given choline and Piracetam®, a pyroglutamate derivative. They found that rats given the Piracetum®/choline combination exhibited (memory) retention scores several times better than those given Piracetum® alone. Results also showed that half the dose was needed when the two were combined (Holford, 2002).

2.7.7.2 Constituents of Advanced Brain Food®

A) Phosphatidylcholine

Phosphatidylcholine (PC) is the presumed active ingredient in lecithin supplements (Holford, 2002). When taken orally it is degraded into the essential nutrient choline.

Phosphatidylcholine is a nutrient that can supply choline, which is needed for cell-membrane integrity and acts as a precursor to the neurotransmitter acetylcholine, which is needed for normal brain function (Holford, 2002). The brain has a voracious appetite for choline. There are two main reasons for the brain's huge need for this nutrient: choline is

required for synthesis of the key neurotransmitter acetylcholine, and it is used for the building and maintenance of brain cell membranes. Acetylcholine is vital for thought, memory and sleep, and is involved in the control of movements (Holford, 2002).

Phosphatidylcholine is absorbed into the mucosal cells of the small intestine, mainly in the duodenum and upper jejunum, following some digestion by the pancreatic enzyme phospholipase, producing lysophosphatidylcholine (lysolecithin).

Reacylation of lysolecithin takes place in the intestinal mucosal cells, reforming phosphatidylcholine, which is then transported by the lymphatics in the form of chylomicrons to the blood. Phosphatidylcholine is transported in the blood in various lipoprotein particles, including very -low -density lipoproteins (VLDL), low -density lipoproteins (LDL) and high -density lipoproteins (HDL). It is then distributed to the various tissues of the body. Some phosphatidylcholine is incorporated into cell membranes (Buckman et al. 1992).

Phosphatidylcholine is also metabolis~~z~~ed to choline, fatty acids and glycerol. The fatty acids and glycerol either get oxidis~~z~~ed to produce energy or become involved in lipogenesis. Choline is a precursor of acetylcholine. Serum choline levels peak between two~~2~~ to six~~6~~ hours after oral intake (Stoll et al. 1993).

Phosphatidylcholine's role in the maintenance of cell- membrane integrity is vital to all of the basic biological processes. These are information flow that occurs within cells from DNA to RNA to proteins, the formation of cellular energy and intracellular communication or signal transduction (Vance, 2003).

Phosphatidylcholine (PC), particularly phosphatidylcholine rich in polyunsaturated fatty acids, has a marked fluidisz-ing effect on cellular membranes (Stoll et al. 1993). Decreased cell- membrane fluidisz-ation and breakdowns of cell -membrane integrity, as well as impairment of cell -membrane repair mechanisms, are associated with a number of disorders including liver disease, neurological diseases, various cancers and cell death (Stoll et al. 1993).

PC, the predominant phospholipid in mammalian membranes, is synthesisz-ed primarily by the Kennedy pathway in which choline is phosphorylated by choline-kinase to phosphor choline, which is converted to CDP-choline and subsequently to PC (Vance, 2003). In this pathway, the conversion of phosphocholine to CDP-choline, catalysz-ed by CTP: phosphocholine cytidylyltransferase (CT), is the rate -limiting step (Vance, 2003).

The precise mechanism of action is not known. The proposed neurologic effects of choline supplements are based primarily on the nutrient's role as a precursor in acetylcholine synthesis. Choline may also influence brain function by effects on phospholipid biosynthesis (Holford, 2002).

Scientists at the University of Alabama's Department of Microbiology in Birmingham used test animals to determine what role phosphatidylcholine might play in cognitive function (Holford, 2001). Before subjecting young and old animals to maze tests in order to evaluate their cognitive abilities, they gave half of the older subjects phosphatidylcholine. While all the young animals learned the maze very quickly, those older animals given phosphatidylcholine learned the maze significantly faster than the control group (Holford, 2001).

Other Proposed Uses of Phosphatidylcholine

Use of lecithin or choline in unipolar mania or rapid-cycling bipolar disorder is based on highly preliminary evidence only (Stoll et al. 1993).

Phosphatidylcholine/lecithin might have value for treatment or prevention of various liver diseases, including alcoholic hepatitis, fatty liver and cirrhosis, chronic and acute viral hepatitis and hepatic failure, although the evidence at present is preliminary and somewhat inconsistent (Vance, 2003).

Based on choline's function as a methyl donor there are at least theoretical reasons to suspect that it might have chemo-preventive properties (Rodgers, 1995).

Preliminary evidence suggests that choline in concert with other methyl donors like folate, methionine, and vitamins B12 and B6 may exert a cardio-protective effect by lowering homocysteine levels (Rodgers, 1995).

B) Phosphatidylserine

A naturally occurring phospholipid found in the brain, phosphatidylserine (PS) influences a number of metabolic and pharmacologic functions (Gesh et al. 2002). Considered to be the "master switch" of cell membrane functions, phosphatidylserine is located primarily in the inner-most area of a cell's membrane and is responsible for directing neurons in communicating more effectively and activating key enzymes involved in the cell communication process (Smith, 1997). PS appears to stimulate the production of the neurotransmitters acetylcholine and dopamine as well as Nerve Growth Factor (NGF). In

this way PS supplementation may help keep neural membranes flexible and thus have a positive effect on cognitive functioning (Smith, 1997).

On the receiving end of the neurotransmitters are the neurotransmitter receptor sites. Information is received here to complete brain function. Any deficiencies here will result in less than optimal brain function (Holford, 2002). These receptor sites are built out of two key nutrients - phosphatidylserine and essential fatty acids, principally the omega 3 fat, DHA. Phosphatidylserine (PS), ~~is~~ found in lecithin, is known to enhance ~~your~~the brain's production of the neurotransmitter acetylcholine (Holford, 2002). Phosphatidylserine, a complex of amino and fatty acids extracted from soy lecithin, which has proven to be a safe, potentially effective therapeutic agent in treating memory deficit disorders and is a frequently~~n often~~ used supplement for attention deficit disorders. The end result can be an increase in both short-~~term~~ and long-term memory (Holford, 2002).

Numerous studies have documented the impact of PS on specific brain neurotransmitters including acetylcholine, serotonin, norepinephrine and dopamine. Many researchers agree that these neurochemical systems are involved in behaviour and cognitive function (Smith, 1997). Several studies have shown a significant improvement in behaviour, concentration, attention and memory when patients supplement with PS daily (Taylor et al. 2000).

Exogenously administered phosphatidylserine stimulates acetylcholine release from the cerebral cortex of rats (Reisbick et al. 1990).

Dopaminergic effects have been seen as well. In addition, phosphatidylserine has been implicated as a universal sign of apoptotic cell death. When the phospholipid is translocated from the inner layer of the cell membrane, its outer membrane presentation is a signal for the damaged cell to be ~~phagocytized~~ phagocytised by macrophages (Engel et al. 1992). Thus exogenous extra-cellular phosphatidylserine might serve as a decoy, preventing unnecessary tissue degradation by activated macrophages. This novel model is supported by earlier work demonstrating suppression of macrophage phagocytic function by phosphatidylserine (Crook et al. 1992).

The therapeutic effect of PS helps against serious mental and neurological problems, and against normal age related memory loss, as demonstrated in a study of 149 people over the age of 50~~fifty~~. The people who had the greatest impairment in their mental faculties improved the most. The benefits remained for up to four weeks after the subjects stopped taking the nutrient. One of the study's authors concluded that phosphatidylserine seems to reverse about ~~twelve~~12 years of mental decline (Holford, 2002).

Phosphatidylserine is also noted to reduce the stress hormone cortisol, which at high levels can prevent the brain from feeding on glucose, thus inhibiting communication among brain cells (Engel et al. 1992). It is effective against seasonal affective disorder, ADHD, Parkinson's disease and Alzheimer's disease (Borak, 2002).

Phosphatidylserine has been studied for about 50 years and has an outstanding track record in both human and animal studies for supporting healthy cognitive function. Results consistently demonstrate improvements in attention and arousal, verbal fluency and memory in aging people with mental deterioration (Holford, 2002).

Phosphatidylserine has been the subject of many human clinical trials regarding memory loss, mood, cognitive performance, learning ability and stress. Many studies show that phosphatidylserine can optimis~~z~~e cognition. In the most famous human study, researchers gave 300 mg of Phosphatidylserine a day for 12 weeks to 149 subjects over 50. Various memory and learning tests were administered before and after (Holford 2001). The results showed that Phosphatidylserine managed to raise cognitive performance to the levels typical for persons as much as 12 years younger (Baizier, 2001).

Reported side effects of phosphatidylserine in clinical trials are rare and are usually limited to mild gastrointestinal distress (Gesh et al. 2002). In double-blind trials, biochemical evaluations have shown no adverse effects (Engel et al. 1992). Oral dosages in rodent and dog studies showed no defined organ system toxicity, and LD50 values were either not determinable or were very high (Cenacchi et al. 1993). Phosphatidylserine has been found non-teratogenic in rats and rabbits. Mutagenic testing was negative (Blokland et al. 1999).

C) Vitamin B3

Vitamin B3 is a member of the B complex that is critical for energy production and well - being on many levels, especially heart health and optimal circulation. It is involved in over 50~~fifty~~ reactions that turn sugar and fat into energy (Holford, 2001).

It is also needed for amino acid metabolism and is involved in converting fats into compounds known as eicosanoids, hormone like agents that control our body's metabolic pathways (Smith, 1997).

With regards to brain function, Niacin has significant benefits in reversing schizophrenia. As early as 1957 Dr. Humphrey Osmond and Dr. Abram Hoffer from Saskatchewan in Canada proved that supplementing with niacin normalis~~z~~ed behaviour in those diagnosed with schizophrenia. Dr. Hoffer, who has now treated over 5000 schizophrenic patients, claims an 80% success rate using niacin and other connector nutrients. Niacin and niacinamide doubled the two-year recovery rates from this mental disease after just five weeks (Holford, 2002).

D) Gingko Biloba

As one of the most well researched herbs, gingko has been shown to improve short~~-~~term and age related memory loss, slow thinking, depression, circulation and blood flow directly to the brain (Holford, 2001).

A review of ten studies testing gingko's effects on people with circulation problems, carried out at the University of Limburg in the Netherlands, found significant improvement in memory, concentration, energy and mood (Holford, 2003).

It appears that by increasing cerebral blood flow, and therefore oxygen and glucose utilis~~z~~ation, gingko offers relief of the presumed "side effects" of aging and may offer significant protection against their development (Crook et al. 1992).

In addition, experimental and clinical studies show that gingko increases the rate at which information is transmitted at the nerve cell. It has also been shown to normalis~~z~~e the acetylcholine receptors in the hippocampus of aged animals, to increase cholinergic

transmission and to address many of the other elements of Alzheimer's disease (Cenacchi et al. 1993; Holford, 2001).

E) Vitamin B12

Although cobalamin, as vitamin B12 is technically termed, appears in all animal foods and can be manufactured by beneficial bacteria in the gastrointestinal tract, a deficiency and its health consequences are never far away, especially in vegetarians (Holford, 2002).

Absorption depends entirely on a healthy intestinal supply of "intrinsic factor" which is a substance made in the stomach that latches onto B12 and draws it into the bloodstream. With age we generate less and less intrinsic factor, one of the reasons anyone older than fifty is vulnerable to a deficiency (Fioravanti et al. 2004).

A broad range of emotional and cognitive abilities relies on an optimal amount of Vitamin B12. In cognition tests of elderly people, for instance, those who had the poorest scores had the lowest blood measurements of cobalamin (Holford, 2002). People diagnosed with depression had low levels of cobalt, the mineral that forms the centre of the vitamin B12 molecule.

Restoring a healthier blood concentration relieves symptoms of dementia and confusion for many people (Holford, 2001). It also contributes to minimi~~s~~ing the mental deterioration that occurs in AIDS.

F) Folic acid

Research at King's College Hospital and the Institute of Psychiatry in London found that a third of all patients with either severe depression or schizophrenia were deficient in folic acid (Fioravanti et al. 2004). Supplementing folic acid for six months made a big difference in their symptoms and ability to relate (Holford, 2002). Folic acid, together with B12, is needed to convert the amino acid L-tryptophan into serotonin and tyrosine into dopamine (Holford, 2002).

G) Pantothenic acid

Pantothenic acid (vitamin B5) is essential to convert choline, such as phosphatidylcholine, into the neurotransmitter acetylcholine, the key memory molecule (Holford, 2002). Without this vitamin, supplementation of choline of any kind would be of little value (Engel et al. 1992).

Pantothenic acid is involved in the breakdown of carbohydrates, fats and protein and in the production of various enzymes, pantothenic acid is needed by the adrenal cortex for the secretion of glucocorticoids (Fioravanti et al. 2004).

H) Pyroglutamate

Pyroglutamate (2-oxo-pyrolidone carboxylic acid, or PCA) is an amino acid found in vegetables, fruits, dairy products and meats (Holford, 2001). Arginine is a non-essential amino acid and is abundant in protamines and histones, which are both proteins associated with nucleic acids and was first isolated in 1895 from animal horn

(Kolesnichenko et al. 1999; Murray et al. 1998). Pyroglutamate is also present in large amounts in the human brain, cerebrospinal fluid and blood (De Freudis, 1998).

A key brain chemical in enhancing memory and mental function is the amino acid pyroglutamate and its derivatives. Being on the receptor end of brain communication, pyroglutamate improves learning, memory, concentration and the speed of reflexes (Holford, 2002). Pyroglutamate is known to have a number of remarkable cognitive-enhancing effects (Holford, 2002).

Toxicity and symptoms of high intake of Pyroglutamate

Although ~~R~~rare, ~~but~~ symptoms of massive dosages may include skin thickening and coarsening of the skin, weakness, diarrhoea, nausea, as well as increasing the activity of some viruses. For this reason people suffering from herpes should avoid high dosages. Pregnant and lactating women and people suffering from schizophrenia should also avoid high dosages (Kolesnichenko et al. 1999).

So-called "smart drugs" have been developed based on slight variations of this substance helping with learning and memory related problems (Borak, 2002; Holford 2001). Numerous studies using these "smart drugs" have proven to enhance memory and mental function, not only in those with pronounced memory -decline but also people with so-called normal memory function (Blokland et al. 1999).

2.8 PROGNOSIS

Although orthodox treatment may improve many aspects of general behaviour in the ADHD child, studies have failed to show it to be effective in improving school achievement (NIH Consensus Statement, 1998).

Prognosis remains unchanged, whether the child is on allopathic drugs or no medication (Karen et al. 1993; Safer and Allen, 1976).

Follow -up studies on children with ADHD have found that they do not grow out of their difficulties (Biederman, 1996; Bird, 1996). Long-term studies on ADHD children have indicated that only about 25% ~~percent~~ of these children make good adjustments to adult life. Approximately 15% ~~percent~~ of ADHD children become psychotic at some stage during their adult lives and 40 ~~to~~ 60% ~~percent~~ continue to have significant concentration and impulse control difficulties (Borak, 2002 Leary, 1994).

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2.8.1 Adult ADHD

Although ADHD is primarily regarded as a childhood disorder, it is~~, however,~~ being increasingly identified that children with ADHD grow up to experience various psychological problems such as chronic depression, drug dependencies and antisocial behaviour (Klein and Mannuza, 1991). Morrison (1980) found an increased incidence of violence and legal problems, less education and low work status in adults who were diagnosed as suffering from ADHD as children. Subsequently Leary (1994) found that adolescents (with a history of ADHD) showed increased aggressive behaviour and conduct disorder and as adults. He found a higher incidence of substance abuse, court summonses and involvement in motor vehicle accidents (Leary, 1994).

ADHD problems that may persist into adolescence and adulthood may manifest as-

- Impulsiveness and attention deficiency
- Academic failure
- Low self-esteem
- Mood and anxiety disorders
- Depression and irritability (Haislip, 1996)
- Drug use disorders
- Antisocial personality disorders (25% ~~percent~~)
- Impulsiveness (50% ~~percent~~) (Sierles, 1993).

2.9 CONCLUSION

ADHD is a socially and academically debilitating condition seen in 10 ~~to~~ 20% ~~percent~~ of school- aged children. Inability to maintain concentration in the classroom environment is an important factor resulting in academic maladjustment. It has been shown that ADHD is not primarily a childhood disorder and that symptoms do persist into adulthood (Strauss, 2000).

Ritalin®, the drug of choice, is effective in improving concentration, memory, frustration and anger, but it is ineffective in up to 30% of suffers (Picton, 1997). Ritalin®, which physicians consider to have only short-term effects, may initiate changes in the brain structure and function that remain after the therapeutic effects have dissipated (Baizer, 2001).

Methylphenidate does not make a difference in the long-term outcome of ADD/ADHD (Breggin, 2001; Holford, 2001). A recent study carried out at Montreal Children's

Hospital discovered that at the end of five years, hyper-kinetic children who received stimulant drugs (Ritalin® or Chlorpromazine®) did not differ significantly from children who had not received these drugs (Karen et al. 1997). Although it appeared that hyperactive children treated with Ritalin® were initially more manageable, the degree of improvement and emotional adjustment was essentially identical at the end of five years to that seen in a group of children who had received no medication at all (Breggin, 2002; Holford, 2001).

Present drug management involves the long-term use of powerful drugs which can lead to dependency, whilst the long-term effects are not yet conclusive. There is no data to conclusively demonstrate that these drugs improve learning over long periods (NIH Consensus Statement, 1998). Many parents are dissatisfied with the use of drug therapy due to the adverse side -effects and lack of clinical response, and are thustherefore seeking alternatives (Whalen and Henker, 1991; Pooley, 1999). Seven to ten percent of the children in America take some form of psychostimulants at some point in their school career (Breggin, 2000; Holford, 2002). Data has shown a 1000% percent increase in drug abuse injury reports involving Ritalin in the 10-14ten to fourteen year age group (Haislip, 1996).

Homoeopathy provides an alternative for many people seeking medication without fear of dependency or undesirable side effects. Homoeopathic remedies have minimal to no side effects, should not produce dependency and are considered safe to use for all age groups (Jouanny, 1993).

A homoeopathic alternative to drug therapy in ADHD has not yet been extensively researched and may provide a relatively inexpensive and safe substitute to drug therapy.

Advanced Brain Food® is a nutritional supplement formulated to meet the needs of children with learning, concentration and behavioural difficulties. According to research done by Holford in the United Kingdom (1998), the individual nutrients in Advanced Brain Food® have been shown to enhance neurologic function and learning capabilities as well as assisting in moderating blood sugar changes.

This combination of nutrients offers the perfect solution in assuring that children receive the appropriate nutrients essential for growth (Holford, 2000).

The aim of the study was to evaluate the efficacy of the homoeopathic combination preparation Quietude®,and a nutritional supplement, Advanced Brain Food® in the management of ADHD in children. This study proposes to show that Quietude® and/or Advanced Brain Food® could be used as an alternative to methylphenidate hydrochloride or other orthodox drugs in the management of ADHD, with particular regard to concentration abilities, hyperactivity and impulsivity.

CHAPTER 3

MATERIALS AND METHODS

3.1 STUDY DESIGN

The purpose of this clinical trail was to evaluate the relative efficacy of a Nutritional Supplement (Advanced Brain Food®) and a Homoeopathic Complex (Quietude®) in the management of Attention Deficit Disorder with associated Hyperactivity of school going boys between the ages of ~~8~~ eight and 13 by means of an ADHD Rating Sale (DuPaul et al 1998; Middleborough, 2001), Student Behaviour Log (Lazear,1999) and Children Checking Task (Lezak, 1983; Strauss, 2000).

Research conducted by Middleborough (2001) showed that the ADHD Rating Scale is aimed at evaluating hyperactivity and. impulsivity. Due to the distinction between the two different components (hyperactivity and impulsivity) this scale can be used to assess

improvement in either one of these areas or as a total score (DuPaul et al. 1998), thus the reason for inclusion of such an assessment technique in the research.

This research incorporated subjective data only. It was therefore decided to use as many assessment scales as possible, to eliminate bias answers that could be given by participants in the trial. Middleborough (2001) states that the ADHD rating scale could be influenced by several factors e.g. workload of parent, schoolwork, demands placed upon the child etc., hence ~~Thus~~ the ~~reason for~~ incorporation~~g~~ of one more assessment technique (Student Behaviour Log) that was to be completed by the parents/guardians participating in the trial.

This was a clinical trial in which two experimental groups were compared to each other.~~;~~ T~~t~~he objective was to determine whether Advanced Brain Food® or Quietude® could be used as an alternative treatment for ADHD with respect to cognitive abilities and behavioural changes of an ADHD subject. The 20 participants were randomly divided into two groups of ten prior to the study:

- Group A was the treatment group receiving a nutritional supplement (Advanced Brain Food®).
- Group B was the treatment group receiving a homoeopathic combination in syrup form (Quietude®).

This study was a randomised controlled clinical trail without crossover. Results for the Children's Checking Task (CCT), Student Behaviour Log (SBL) and ADHD Rating Scale from group A and group B were compared against each other.

Three results were obtained from group A and group B subjects with regards to the children checking task. Four results were obtained from the parent/guardian of the subjects assigned to group A and B with respect to the ADHD Rating Scale and SBL.

During interviews held with the prospective participants, it was explained that the two groups were randomly allocated prior to the study and that the subjects were to be allocated one or the other intervention without the research student knowing what medication was allocated to which subject. It was also explained that following the study these participants would be given the option of trying any of the two treatments at no cost to the participant for an additional period of one month.

3.2 LOCATION OF THE STUDY

Permission to conduct the study at Dr. Leon Strauss's consulting rooms (Corner of 1st and Linksfield Avenue, Edenvale) was requested in a written application addressed to Dr. Strauss to make use of the clinic facilities (Appendix A). The two different treatment interventions (Advanced Brain Food® or Quietude®) were dispensed from this location.

3.3 ADVERISING AND RECRUITMENT PROCEDURES AND SAMPLING

The Hyperactivity Support Group of South Africa was approached to obtain participants for the research trial. An advertisement of the proposed trial was placed in local papers (Bedfordview Chronicle and Boksburg Advertiser), advertising a study on the alternative treatment of children with ADHD. This advertisement ran for six~~6~~ consecutive weeks in the abovementioned advertising papers. Posters were placed at childcare centres and primary schools in the central Johannesburg area. Permission was obtained from ten~~10~~

Dis-Chem Pharmacies (Central Gauteng) to advertise there by means of a poster (Appendix D).

Twenty subjects were recruited as a result of responding to the advertisements by means of convenience sampling.

3.4 SELECTION CRITERIA

Interested parents who called in response to the advert were briefed on the details of the study. Those who were interested were assessed according to the following criteria:

Inclusion Criteria:

- Subjects/participants must be males.
- Subjects/participants must be between the ages of eight~~8~~ and 13 years of age.
- Subjects/participants must be in possession of a doctor's certificate, which diagnoses them as having ADHD according to the DSM-IV criteria. ~~,~~ ~~t~~The diagnosis can be made by a Paediatrician, a General Practitioner and in conjunction with a Psychologist who is in the possession of a completed Conner's Rating Report for the subject.
- Methylphenidate (Ritalin®) must be the treatment suggested for the subjects presenting with ADHD, or the subjects must be taking Ritalin® for a time period of at least three months prior to the study.

- Participants must for the period of one week prior to the study and for the duration of the study abstain from any other medication or treatment for their condition. [The half-life of Ritalin® is about two~~2~~ hours, and after four hours the effect of the drug tends to drop dramatically. It is also available in a slow release form with a half-life of eight~~-~~ hours (Ritalin SR package insert)]. Drug metabolites take approximately 72 hours to clear out of the bloodstream (Karen et al. 1997)
- Subject must ~~that~~ have signed an assent form (Appendix C).
- Subjects must be ~~that are~~ in ~~the~~ possession of a signed consent form from their parents/guardians. (Appendix B).

Exclusion Criteria:

- Participants who suffer from epilepsy cannot be taken into the research due to the effects of Phosphatidylcholine (PC) and Phosphatidylserine (PS) on this condition. PS and PC are direct precursors to the neurotransmitter acetylcholine (Holford, 2001). It may be considered dangerous to epileptics for the following reasons:

    i. Acetylcholine may block GABA (gamma aminobuteric acid) in the cerebral cortex and this can provoke seizures.

ii. Acetylcholine is considered as an excitatory neurotransmitter in the cerebral cortex and therefore ~~thus it~~ has the ability to provoke seizures in epileptic patients (Davidson, 1994).

- Patients who cannot abstain from the relevant chronic allopathic medication for the duration of the study.
- Patients that do not have a signed consent (Appendix D) and assent form (Appendix C) to confirm that they are partaking in the research study out of their own free will and are aware of the fact that they can withdraw from the study at any time without giving a reason.

A meeting was held with the parent of each prospective subject for the study and when they conformed to all the above-~~-~~mentioned criteria, the purpose and method of the study was fully explained to them. Parents/Guardians of the children participating in the trial received a Subject Information Letter (Appendix F) that they read and ~~had~~ were given the ~~an~~ opportunity to raise questions regarding the research study. It was explained to the parents that they were free to discontinue the trial at any time. They were also requested not to introduce any additional measures (e.g. change of normal diet, change in daily vitamin supplementation etc.) that would benefit the child's ADHD, during the trial.

When both child and parent agreed to participate, the child was given an informed assent form (Appendix C) which again outlined the details of the study in simple words for the child's understanding. All participant's parents/guardians were required to sign a consent form (Appendix D).

The physician~~'~~s of children participating in the trial were given full access to information on the trial and test results.

3.5 SAMPLE GROUP

The sample group ~~was~~ initially chosen for this research was a total number of 30 boys between the ages of eight~~8~~ and 13 years. It was initially thought that this would be the minimum number necessary to provide a good representation of children diagnosed with the disorder and to provide statistically significant results. After eight~~8~~ months of canvassing for participants it was decided to reduce this number to a total of 20.

The decrease in the sample group was proposed by the researcher and after consultation with the statistician at the University of the Witwatersrand. D~~d~~ue to various circumstances, (See Chapter 5)~~.~~, i~~I~~t was decided that statistical methods on a smaller sample group (n=20) will represent an accurate assessment of all assessments used. The decrease in sample group was discussed with both supervisors in the research trial and was accepted.

The sample was chosen by means of the convenience sampling method. The advertisements placed at ten~~10~~ Dis-Chem Pharmacies that were selected are distributed in areas with varied income and racial preponderance;~~,~~ no attempt was made to focus on any particular racial group. The demographics of ADD/ADHD have until now shown that the disorder is found equally in all races but that the reported cases are often restricted to middle and higher income groups or groups with access to medical and educational

services (Middleborough, 2001; Picton, 1997). In the final group 15 of the participants were Caucasian, 4 were Asian and 1 was African.

3.6 RANDOMISATION

Mrs. Kim John's (Chief Pharmacist, ~~-~~Dischem Pharmacies) conducted the randomi~~s~~z~~z~~ation of this study, which~~. The randomization~~ was done in a double-blind manner, so that neither the researcher or the parent/guardian would know to which group the subject was assigned ~~to~~. It was important to do the randomi~~z~~s~~s~~ation in this manner, because the two interventions used (Advanced Brain Food® and Quietude®) were administered in different forms~~:,~~ Advanced Brain Food® is a tablet and Quietude® is a syrup.

Prior to the commencement of the study, a list of numbers was compiled ranging from 1 to 20. The person that was responsible for the randomi~~s~~z~~z~~ation allocated a specific intervention to be used (Advanced Brain Food® or Quietude®) to each of these numbers on the list. Ten numbers were randomly allocated to group A (Advanced Brain Food®) and the remaining 10 numbers were allocated to group B (Quietude®). The researcher was not made aware of this list until all subjects completed the clinical trial.

By the researcher not knowing which subject receives which treatment, the study could ~~not~~be considered as being a double blind study.

As the subjects presented themselves for the initial consultation, they were allocated a number in sequence ranging from one~~1~~ to 20. These numbers was noted on the consultation form by the researcher. Once the patient was accepted into the study they

were taken through to the dispensing facilities at Edenvale consulting rooms where the researcher then left them to receive their medicines according to the number that was allocated to them. The Advanced Brain Food® being unavoidably visually distinguishable from the homoeopathic preparation (Quietude®) necessitated the absence of the researcher at all times when medicines were dispensed. Patients were also informed not to discuss the type of medication they received on all subsequent consultations with the researcher. Every effort was made not to let the research student know what treatment the participant was taking. If a query should arise with any of the two treatment interventions, the parent/guardian was instructed to discuss it with Dr. Strauss (research supervisor).

Seeing that this study involved a vulnerable group, there was no placebo group (both groups of subjects received an intervention, of either Advanced Brain Food® or Quietude®), and each participant served as his own control.

The research committee at Durban Institute of Technology declined the introduction of a placebo group because they felt that inclusion of such a group (receiving no medication) might be detrimental to the participant partaking in the study with regards to social and academic interactions.

3.7 INTERVENTION

Group A

They received the nutritional supplement (Advanced Brain Food®) in tablet form.

Bioharmony® SA supplied the Advanced Brain Food® tablets from their Patrick Holford Range in an unmarked plastic bottle with a total of 90 tablets in each of the PVC containers. The bottles were labelled as:

Take one~~1~~ tablet in the morning and one tablet mid-afternoon with meals.

A highly qualified pharmaceutical technical team who guarantee the quality and efficacy of each formulation supports Bioharmony® SA's manufacturing arm. The products are manufactured in a fully pharmaceutical laboratory licensed and registered with the Medicines Control Council of South Africa (Bioharmony® SA).The batch number of the stock used was 6ER0430 with an expiry date of 04 /2006.

Group B

They received the homoeopathic complex (Quietude®) in syrup form. Bower Bartlett (Pty) Ltd supplied the Quietude® Syrup in 200ml amber glass bottles. The batch /lot number of the stock used was M4020776 with an expiry date of Feb 2008. On receiving the 200ml amber glass bottles from the supplier, they were decanted into a 500ml amber glass bottle, to obtain enough Quietude® syrup for the trial period of 6 weeks at a dosage of 10ml a day. The amber glass bottles were labelled as:

Take 5ml (1 teaspoon) in the morning and 5ml mid-afternoon with meals

As the patients were being treated and evaluated at home the researcher relied upon the honesty and integrity of the parents/guardians to ensure that they complied with all instructions. Only once they were sure of their responsibilities were they taken to the

dispensary (at Edenvale) to receive their respective medicines. All participants were contacted on a fortnightly~~two weekly~~ basis to enquire about compliance and any difficulties they may have been experiencing~~.~~, A~~a~~ny who had been unable to conform were excluded from the study.

3.8 MEASUREMENT TECHNIQUES

3.8.1 THE ADHD RATING SCALE- IV

The ADHD Rating Scale – IV (Appendix G and H) was developed by G. J. DuPaul, T. J. Power, A. D. Anastopoulos and R. Reid in 1998. It was developed for use by clinicians and doctors in research. It can also be used for individual patient assessment to track changes in the areas of inattention and hyperactivity/impulsivity that might be exhibited by a patient. For the purpose of this research, only the mean scores of each category (inattention or hyperactivity/impulsivity or total scores) were used for analysis.

The home version was used for the purpose of this study as the researcher felt that it would be easier to gain the parent~~'~~s' co-operation than the teachers. It was further felt that teachers of the respective subjects could omit bias answers.

The questionnaires (Appendix G) were handed to the parents at the initial interview where it was explained to the parent how to use the questionnaire. Parents were asked to read through the questionnaire to ensure that they understood all ~~of~~ the questions.

These questionnaires were completed on the following occasions:

- **No. 1** Prior to commencement of the trial which served as the baseline for the study
- **No. 2** After the first two weeks of treatment.
- **No. 3** After for~~4~~ weeks of treatment.
- **No. 4** After six ~~6~~ weeks of treatment, the end of the trial period.

A total of four~~4~~ questionnaires were completed for each participant with a minimum of three consultations.

Parents were asked to ensure that the completion of the questionnaires was always done by the same person and not by different parents as this would have an influence on the reliability of the data collected. Where possible the initial questionnaire was filled out at the first consultation, ~~however~~although in some situations only one parent/guardian was present and so it was decided that the questionnaire would be completed at home where both parents would provide input. A follow-up consultation was held at the completion of each participant's six weeks where children and parents were given an opportunity to raise any questions.

3.8.2 THE STUDENT BEHAVIOR LOG

This questionnaire was initially intended to be completed by the teachers of the relevant participants involved in the study, but Durban Institute of Technology Ethics Committee felt that a certain amount of bias~~ness~~ would result from this and ~~thus~~therefore only parents/guardians involved in the study were required~~had~~ to complete this questionnaire.

The questionnaires (Appendix G) were handed to the parents at the initial interview where it was explained to the parent how to use the questionnaire. Parents were asked to read the questionnaire to ensure that they understood all ~~of~~ the questions. The researcher explained to the parents/guardians how to complete th~~is~~e log chart.

The student behaviour log was completed on the following occasions:

- **No.1** Prior to commencement of the trial (Baseline for the Study).
- **No. 2** Two weeks whilst the subject is receiving treatment.
- **No. 3** After four~~4~~ weeks of treatment.
- **No. 4** After six~~6~~ weeks of treatment, the end of the trial period.

Once again, parents were asked to ensure that the completion of the questionnaires was always done by the same person and not by different parents as this would have an influence on the reliability of the data collected. Where possible, the initial questionnaire was completed at the initial interview.

3.8.3 CHILDREN'S CHECKING TASK (CCT)

(Appendices K1-K5)

This test was administered individually to each child three times during the course of the clinical trial. Before starting the test each child completed a practice sheet (Appendix

K1) to make certain he understood the test. Each page was marked individually and a percentage score was calculated for letters, numbers, symbols, and words.

Each child was seen individually by the researcher, in the same environment for each test. While the child was completing the CCT, the participating parent filled out the Student Behaviour Log (SBL) in a separate room. During the meetings, observations of the child's behaviour were made and any difficulties experienced were discussed with the parent.

Test results for the CCT and Student Behaviour Log were recorded separately on marking sheets as each test was carried out (Appendices L and M espectively).

3.9 DATA ANALYSIS

3.9.1 STATISTICAL METHODS AND ANALYSIS

This study comprised of quantitative subjective data only, the score of which were scores obtained for the ADHD Rating Scale, Student Behaviour Log (SBL) and Children's Checking Task (CCT), completed at various time intervals.

Hypothesis testing for: ADHD Rating Scale; SBL; CCT

a) The null hypothesis H_0 states that Advanced Brain Food® would have no beneficial effect in the management of ADHD signs and symptoms in terms of the ADHD Rating Scale (Appendix G), SBL (Appendix J) and CCT (Appendix K1-K5). The

alternative hypothesis ~~states~~ H_1 states that there is a beneficial effect in the management of ADHD signs and symptoms in terms of the ADHD Rating Scale (Appendix G), SBL (Appendix J) and CCT (Appendix K1-K5).

b) The null hypothesis H_0 states that Quietude® would have no beneficial effect in the management of ADHD signs and symptoms in terms of the ADHD Rating Scale (Appendix G), SBL (Appendix J) and CCT (Appendix K1-K5). The alternative hypothesis ~~states~~ H_1 states that there is a beneficial effect in the management of ADHD signs and symptoms in terms of the ADHD Rating Scale (Appendix G), SBL (Appendix J) and CCT (Appendix K1-K5).

c) The null hypothesis H_0 states that there is no difference between the groups at the α=0.05 level of significance. The alternative hypothesis ~~states~~ H_1 states that there is a difference between the groups.

Decision rule for: ADHD Rating Scale; SBL; CCT

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

A) INTER-GROUP COMPARISONS (ADHD Rating Scale; SBL; CCT)

Differences between the two groups were evaluated using Mann-Whitney Test (non-parametric option of the independent sample t-test). In order words, the test was used to

establish if differences existed at any of the evaluations between the group A subjects and the group B subjects. Statistical significance was assumed at P<0.05.

Mann Whitney U-Test

Mann Whitney U test was used to examine significant differences between group A and group B subjects in their assessment scores at the different assessment periods

B) INTRA-GROUP ANALYSIS (ADHD Rating Scale; SBL; CCT)

The Friedman's test was used to examine whether the student~~'~~s' scores change~~d~~s over the observation period .Where statistically significant results were found, the Wilcoxon signed-ranks tests is employed for post hoc testing of significant results.

Friedman test

Mean Ranks (Table labeled **Mean Ranks**): Gives mean rank for each test. Higher mean rank indicate higher scores on the test.

Asymp Sig. (Table labeled **Tests**): gives p-values to assess significance of the analysis. Values ≥~~greater than~~ 0.05 indicate that the findings are not statistically significant.

Wilcoxon Signed Rank Test

Wilcoxon Signed Rank test was used to examine significant differences within group A and group B subjects in their assessment scores at the different assessment periods

3.9.1.1 ADHD Rating Scale

The ADHD Rating Scale score of symptoms were subdivided into three further variables:

- sum of all inattention questions,
- sum of all hyperactivity questions and,
- a total score, being the total sum of the above mentioned variables (total scores for inattention and hyperactivity)

Four sets of readings were taken for each subject. Due to the relatively small sample size (n=20) non-parametric tests were applied to the three variables for analysis.

Statistical Analysis of Data from the ADHD Rating Scale

Statistical analysis was performed using SPSS for Windows 13.0 (SPSS Inc., Chicago, IL, USA).

The data was firstly analy~~s~~ed in terms of an inter-group comparison and secondly an intra-group comparison. Analysis was performed separately for observation group A (Advanced Brain Food®) and group B (Quietude®). Statistical significance was assumed at $P<0.05$.

NOTE:

- ***Score1*** *Baseline/Before Trial Assessment Score*
- ***Score2*** *Two~~2~~ weeks into Trial Assessment Score (Follow-up 1)*

- ***Score3*** *Four~~4~~ weeks into~~T~~-trial Assessment Score (Follow-up 2)*
- ***Score 4*** *~~6~~Six weeks into ~~t~~Trial Assessment Score (Follow-up 3)*

3.9.1.2 Student Behaviour Log

The Student Behaviour Log score of symptoms were sub-divided into six variables:

- Total score for Conduct Problems
- Total score for Inattention
- Total score for Psychosomatic Problems
- Total score for Impulsivity/Hyperactivity
- Total score for Anxiety
- Total score for Hyperactivity Index

Four sets of readings were taken for each subject. Due to the relatively small sample size (n=20) non-parametric tests were applied to the six variables for analysis.

Statistical Analysis of Data from the Student Behaviour Log (SBL)

Statistical analysis was performed using SPSS for Windows 13.0 (SPSS Inc., Chicago, IL, USA).

The data was firstly analy~~s~~sed in terms of an inter-group comparison and, secondly an intra-group comparison. Analysis was performed separately for observation group A (Advanced Brain Food®) and group B (Quietude®). Statistical significance was assumed at $P<0.05$.

NOTE:

- ***Score 1*** *Baseline/Before Trial Assessment Score*
- ***Score 2*** *~~2~~Two weeks into Trial Assessment Score (Follow-up 1)*
- ***Score 3*** *Four~~4~~ weeks into ~~t~~Trial Assessment Score (Follow-up 2)*
- ***Score 4*** *~~6~~Six weeks into-Ttrial Assessment Score (Follow-up 3)*

3.9.1.3 Children Checking Task (CCT)

The CCT score of symptoms were sub-divided into four variables:

- Total sum of scores obtained for letters
- Total sum of scores obtained for numbers
- Total sum obtained for symbols
- Total sum obtained for words

Statistical Analysis of the Data from the CCT

Statistical analysis was performed using SPSS for Windows 13.0 (SPSS Inc., Chicago, IL, USA).

Three sets of readings were taken for each subject. Due to the relatively small sample size (n=20) non-parametric tests were applied to the four variables for analysis.

The data was firstly analy~~z~~sed in terms of an intra-group comparison and, secondly an inter-group comparison. Analysis was performed separately for observation group A

(Advanced Brain Food®) and group B (Quietude®). Statistical significance was assumed at $P<0.05$.

NOTE

- ***Score 1*** *=Baseline/Before Trial Assessment Score*
- ***Score 2*** *=~~3~~Three weeks into Trial Assessment Score (Results for Assessment 2)*
- ***Score 3*** *=~~6~~Six weeks into ~~t~~Trial Assessment Score (Results for Assessment 3)*

3.10 ETHICAL CONSIDERATIONS

The physical risks were minimal but they did include the return of old symptoms if the participants current treatment, if any, was ended which was a requirement of the study. On a positive note, current treatment, using methylphenidate (Ritalin®) recommends the use of "drug holidays" where patients are not treated over weekends and holidays. In light of this, the return of old symptoms will not be a total shock to the patient and parents. Some parents actually refuse to administer Ritalin® to their children although their physician or psychologist prescribed it. Thus, if recruited, in these cases the child would not be denied orthodox medication for the sake of participation in the research project.

It can be argued that conducting the trial during a school term can adversely affect the child's performance at school. A recent study conducted at Technikon Natal (2001) confirmed that doing such a study during school holidays is not desirable due to the fact that the child has more time to relax and is free from stress caused by school and learning, thus results measured would not be an accurate reflection of the efficacy of the

intervention (Middleborough, 2001). This trial was originally designed to be conducted very early during a school term so that possible disruptions in school activities could be minimi~~z~~sed. At a later stage however, parents of subjects who met the selection criteria requested their children be recruited on the grounds that they did not consider the use of Ritalin® (although it was prescribed) thus, participation in the study would not result in denial or access to orthodox medication. Both parties i.e. the parents/guardians and participants were made to sign a consent form and assent form to signify their understanding of this and their agreement to participate in the clinical trial. By conducting the trial no major disruption in social behaviour was expected, because both groups of subjects were receiving a treatment intervention (Advanced Brain Food® or Quietude®) and no placebo group was applicable to the study.

As a matter of courtesy teachers and principals in charge of any participants ~~will be~~were made aware of the child's involvement in this study through an information sheet (Appendix M).

This information sheet (Appendix M) was given to them as soon as the child was accepted into the study. They were also given a contact number for the researcher and supervisor of the study should they have had objections or queries to make. The parents/guardians of the children were also made aware of the fact that they were free to withdraw from the study at any time should this~~it~~ be necessary.

CHAPTER 4

RESULTS

4.1 INTRODUCTION

This chapter details the results obtained from the statistical analysis of the data collected from the two groups in the study using the ADHD Rating Scale IV (Appendix G), Student Behaviour Log (Appendix J) and Children Checking Task - CCT (Appendix K1-K5).

4.2 ADMISSIBILITY OF THE DATA

Only the data collected from the research was accepted for use in this chapter. The data used for the analysis was collected in the manner discussed in Chapter 3.

4.3. RESULTS OF THE ADHD RATING SCALE-IV (Appendix G)

Refer to the attached appendices for the raw data relating to the results.

The lower the number of points scored in each test, the more positive the results were, and vice- -versa. Each test was divided into three categories:

- Score of all inattention questions.
- Score of all hyperactivity/impulsivity questions
- Combined score for the above two categories (total of all scores for inattention and hyperactivity/impulsivity)

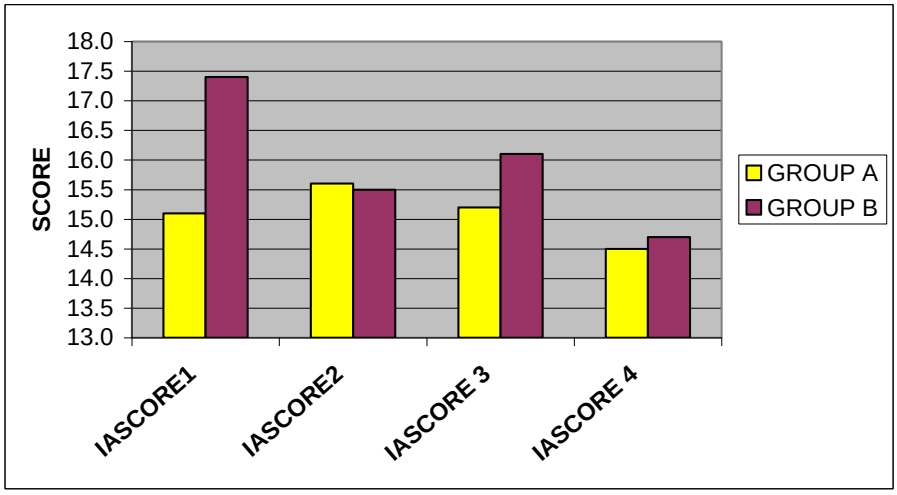
The results reflect the total mean of all the inattention questions, hyperactivity/impulsitivity questions and overall mean scores obtained during the clinical trial. The actual mean scores obtained are reflected in the results and not percentages.

REFRENCE KEY FOR FIGURE 4.1

IASCORE 1	CONSULTATION 1 (BASELINE) INNATTENTION
IASCORE 2	FOLLOW-UP 1 (CONSULTATION 2) - INNATTENTION
IASCORE 3	FOLLOW-UP 2 (CONSULTATION 3) INNATTENTION
IASCORE 4	FOLLOW UP 3 (CONSULTATION 4) INNATTENTION
GROUP A	ADVANCED BRAIN FOOD®
GROUP B	QUIETUDE®

FIGURE 4.1

BAR CHART COMPARING THE MEAN INATTENTION SCORES FOR THE TWO GROUPS



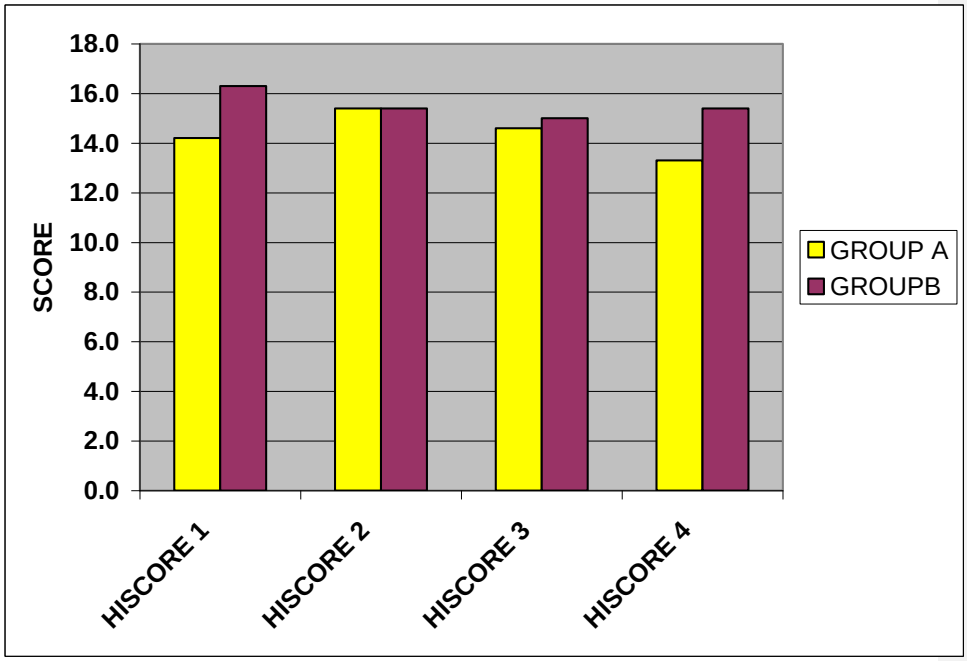
REFRENCE KEY FOR FIGURE 4.2

HISCORE 1	CONSULTATION 1 (BASELINE) HYPERACTIVITY AND IMPULSIVITY
HISCORE 2	FOLLOW-UP 1 (CONSULTATION 2) HYPERACTIVITY AND IMPULSIVITY
HISCORE 3	FOLLOW-UP 2 (CONSULTATION 3) HYPERACTIVITY AND IMPULSIVITY

HISCORE 4	FOLLOW UP 3 (CONSULTATION 4) HYPERACTIVITY AND IMPULSIVITY
GROUP A	ADVANCED BRAIN FOOD®
GROUP B	QUIETUDE®

FIGURE 4.2

BAR CHART COMPARING THE MEAN HYPERACTIVITY/IMPULSIVITY FOR THE TWO GROUPS



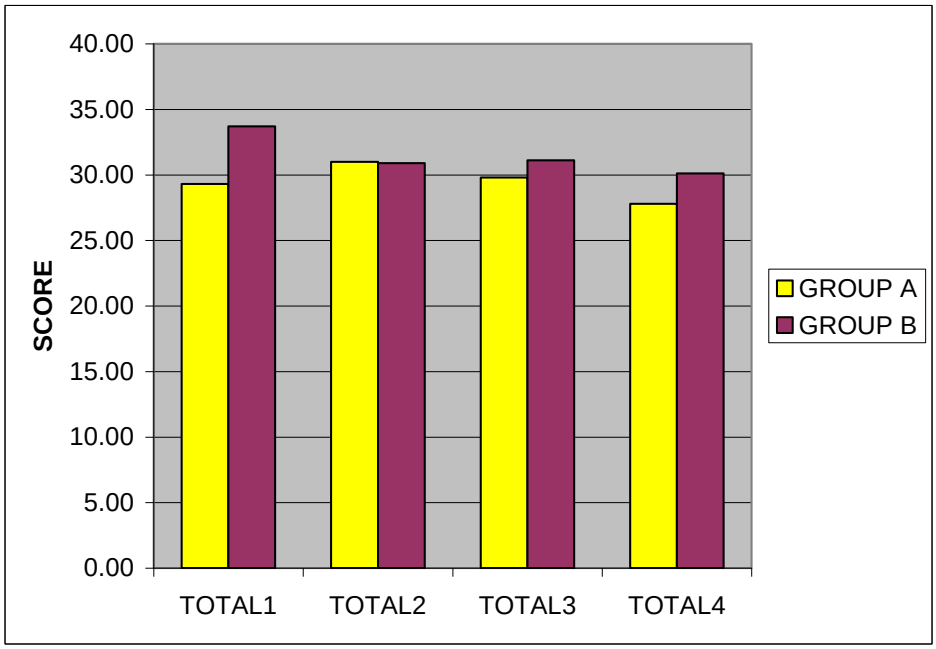
REFRENCE KEY FOR FIGURE 4.3

TOTAL 1	TOTAL OF COMBINED SORES CONSULTATION 1 (BASELINE)
TOTAL 2	TOTAL OF COMBINED SORES FOLLOW-UP 1 (CONSULTATION 2)
TOTAL 3	TOTAL OF COMBINED SORES FOLLOW-UP 2 (CONSULTATION 3)

TOTAL 4	TOTAL OF COMBINED SORES FOLLOW UP 3 (CONSULTATION 4)
GROUP A	ADVANCED BRAIN FOOD®
GROUP B	QUIETUDE®

FIGURE 4.3

BAR CHART COMPARING THE MEAN TOTAL SCORE OF THE TWO GROUPS



4.3.1 INTRA-GROUP ANALYSIS: FRIEDMAN'S TEST

The Friedman's test was used to test for the presence of significant differences between the four consultations in each group. At the $\alpha = 0.05$ level of significance, the test

revealed that there was no statistically significant difference for the inattention, hyperactivity and impulsivity or the total scores between the consultations of the two groups compared ($p > 0.05$ - the null hypothesis H_0 is accepted).

TABLE 4.1

INTRA-GROUP COMPARISON OF THE DATA FOR GROUP A (ADVANCED BRAIN FOOD®) USING FRIEDMANS TEST

SCORES	P-VALUE	CONCLUSION
INATTENTION	0.438	NO DIFFERENCE
HYPERACTIVITY AND IMPULSIVITY	0.616	NO DIFFERENCE
TOTAL SCORE	0.591	NO DIFFERENCE

TABLE 4.2

INTRA-GROUP COMPARISON OF THE DATA FOR GROUP B (QUIETUDE®) USING FRIEDMANS TEST

SCORES	P-VALUE	CONCLUSION
INNATTENTION	0.314	NO DIFFERENCE
HYPERACTIVITY AND IMPULSIVITY	0.801	NO DIFFERENCE
TOTAL SCORE	0.896	NO DIFFERENCE

4.3.2 INTER-GROUP ANALYSIS: MANN-WHITNEY TEST

Mann Whitney U-Test

Mann Whitney U test was used to examine significant differences between group A (Advanced Brain Food®) and group B (Quietude®) subjects in their assessment scores at the four different assessment periods.

At the $\alpha = 0.05$ level of significance, there was no difference between the two groups at the four assessments with regard to Inattention, Hyperactivity/Impulsivity and Total Combined Scores ($p > 0.05$ – the null hypothesis H_0 is accepted).

TABLE 4.3

INTER-GROUP COMPARISON OF THE DATA FOR ALL INNATENTION SCORES FOR GROUP A (ADVANCED BRAIN FOOD®) AND GROUP B (QUIETUDE®)

Tests	Test 1	Test 2	Test 3	Test 4
Mann-Whitney Test	37.000	47.500	42.500	38.500
Asymp. Sig. (2-tailed)	0.324	0.849	0.569	0.380
Exact Sig. [2*(1-tailed Sig.)]	0.353	0.853	0.579	0.393

TABLE 4.4

INTER-GROUP COMPARISON OF THE DATA FOR ALL HYPERACTIVITY /IMPULSITVITY SCORES FOR GROUP A (ADVANCED BRAIN FOOD®) AND GROUP B (QUIETUDE®)

Tests	Test 1	Test 2	Test 3	Test 4
Mann-Whitney Test	42.000	46.500	48.500	37.000
Asymp. Sig. (2-tailed)	0.544	0.791	0.909	0.320
Exact Sig.[2*(1-tailed Sig.)]	0.579	0.796	0.912	0.353

TABLE 4.5

INTER-GROUP COMPARISON OF THE DATA FOR ALL TOTAL SCORES OBTAINED FOR GROUP A (ADVANCED BRAIN FOOD®) AND GROUP B (QUIETUDE®)

Tests	Test 1	Test 2	Test 3	Test 4
Mann-Whitney Test	39.000	49.000	44.000	38.500
Asymp. Sig. (2-tailed)	0.405	0.940	0.650	0.383
Exact Sig. [2*(1-tailed Sig.)]	0.436	0.971	0.684	0.393

4.4 RESULTS OF THE STUDENT BEHAVIOUR LOG (Appendix M)

Raw data for each participating child can be found in the attached appendices (Appendix M, Appendix L). Factor and mean scores have been given individually for each factor of the Student Behaviour Log assessments. The sample has been divided into two groups.

The Student Behaviour Log (SBL) results have been divided up into their respective categories and will be discussed individually below.

The Hyperactivity Index is the overall measure of hyperactivity, taking into account typical ADHD symptoms. The remaining five categories are measures of single common problems typically seen in ADHD (Strauss, 2000). Lower scores in each factor of the Student Behaviour log indicate positive results and vice versa.

FIGURE 4.4

BAR CHART COMPARING THE MEAN TOTAL SCORES OF GROUP A (ADVANCED BRAIN FOOD®) AND GROUP B (QUIETUDE®) FOR CONDUCT PROBLEMS

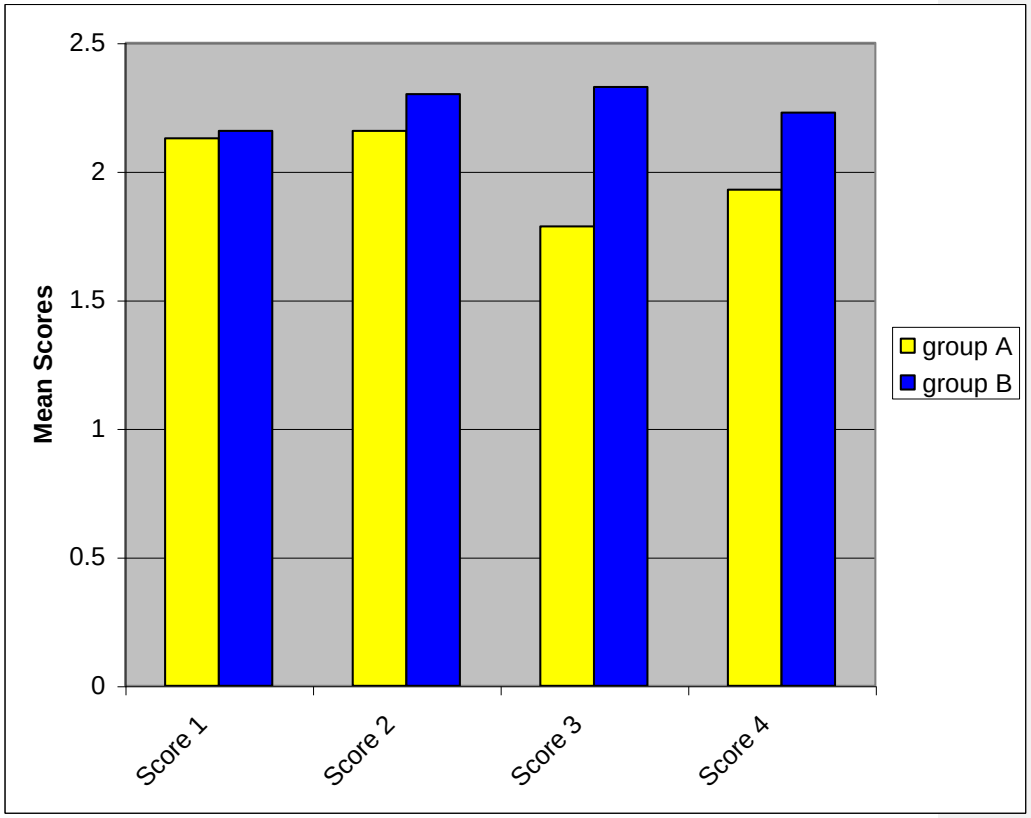


FIGURE 4.5

BAR CHART COMPARING THE MEAN TOTAL SCORES OF GROUP A (ADVANCED BRAIN FOOD®) AND GROUP B (QUIETUDE®) FOR INNATENTION

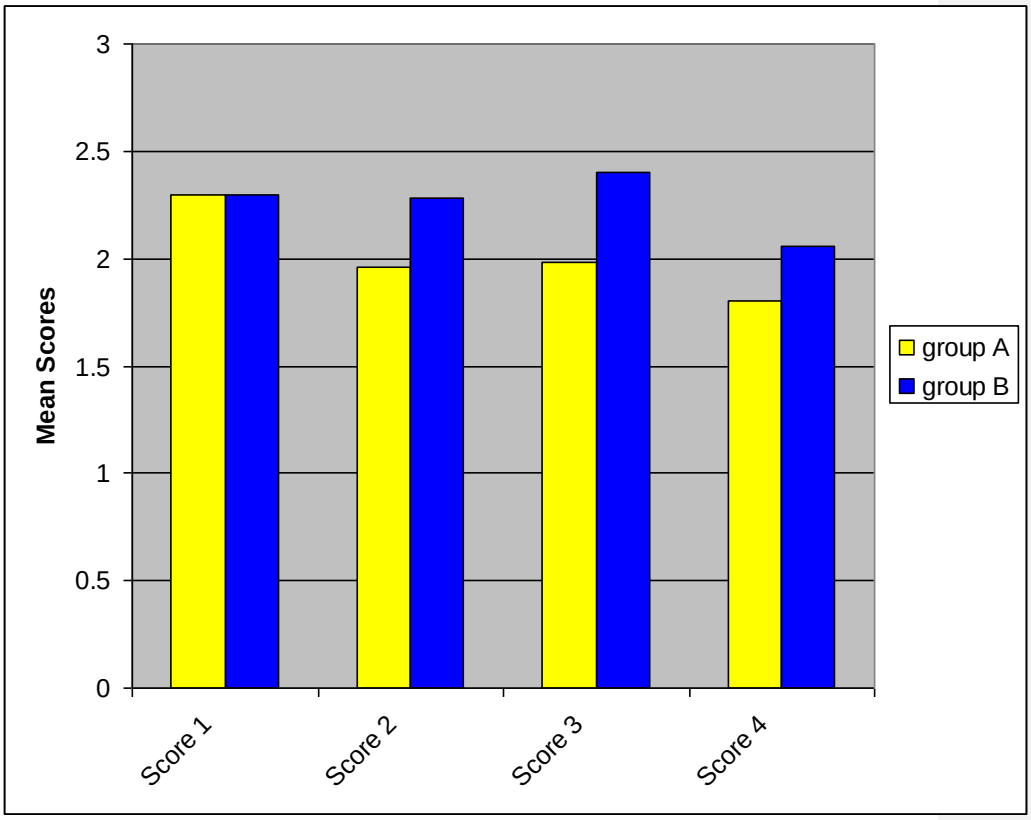


FIGURE 4.6

BAR CHARTS COMPARING THE TOTAL MEAN SCORES OF GROUP A (ADVANCED BRAIN FOOD®) AND GROUP B (QUIETUDE®) FOR PSYCHOSOMATIC PROBLEMS

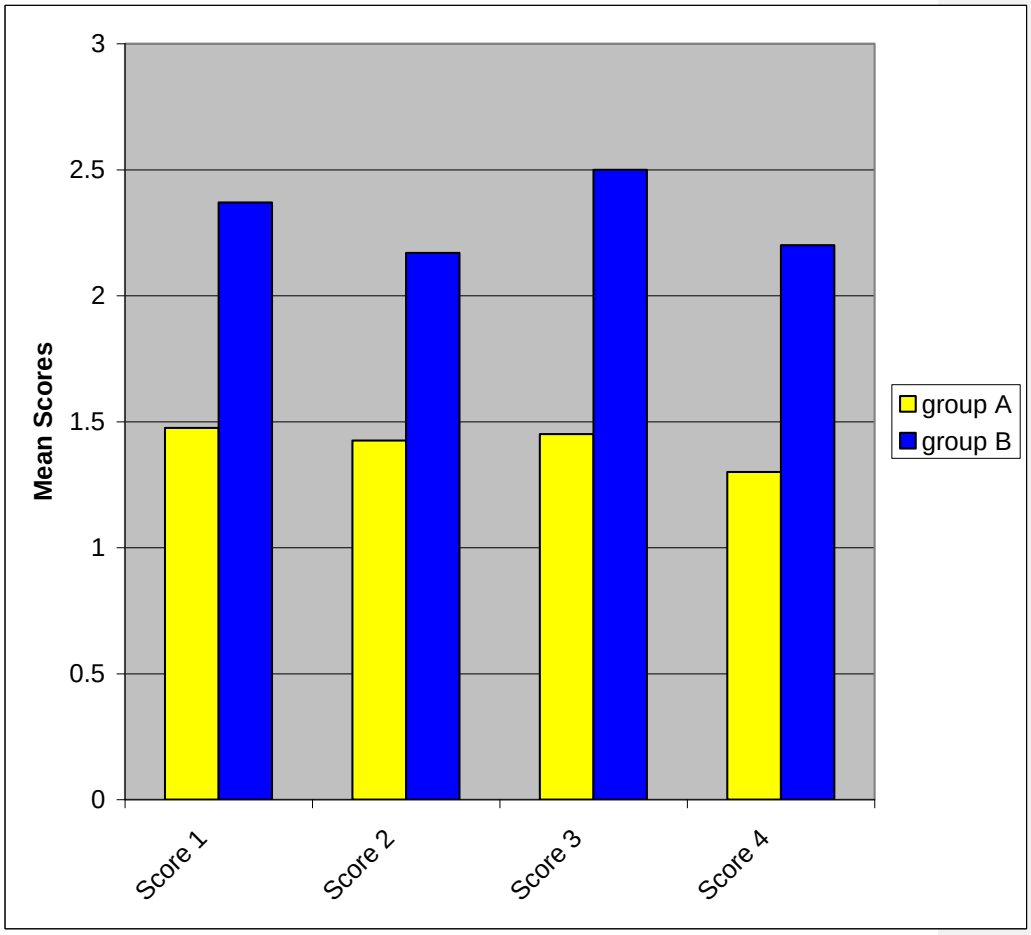


FIGURE 4.7

BAR CHARTS COMPARING THE MEAN TOTAL SCORES OF GROUP A (ADVANCED BRAIN FOOD®) AND GROUP B (QUIETUDE®) FOR IMPULSIVITY

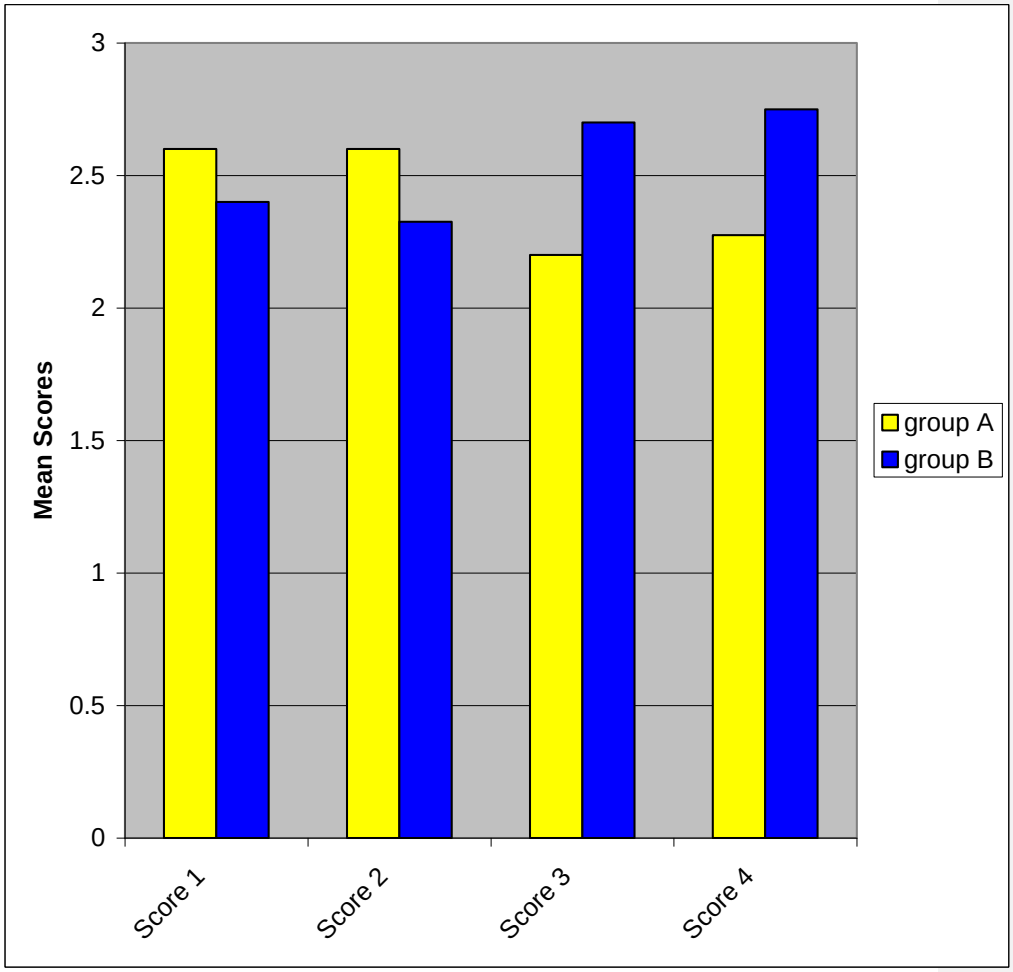


FIGURE 4.8

BAR CHART COMPARING THE MEAN TOTAL SCORES OF GROUP A (ADVANCED BRAIN FOOD®) AND GROUP B (QUIETUDE®) FOR ANXIETY

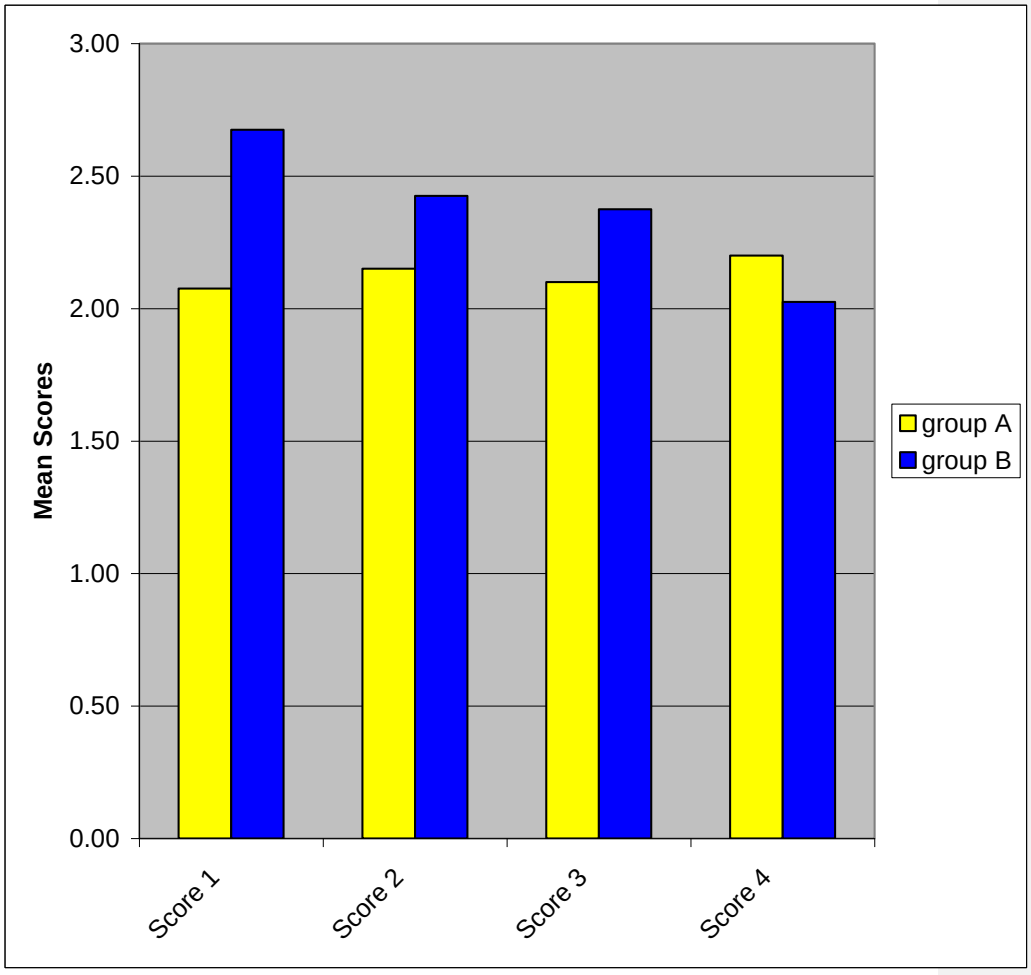
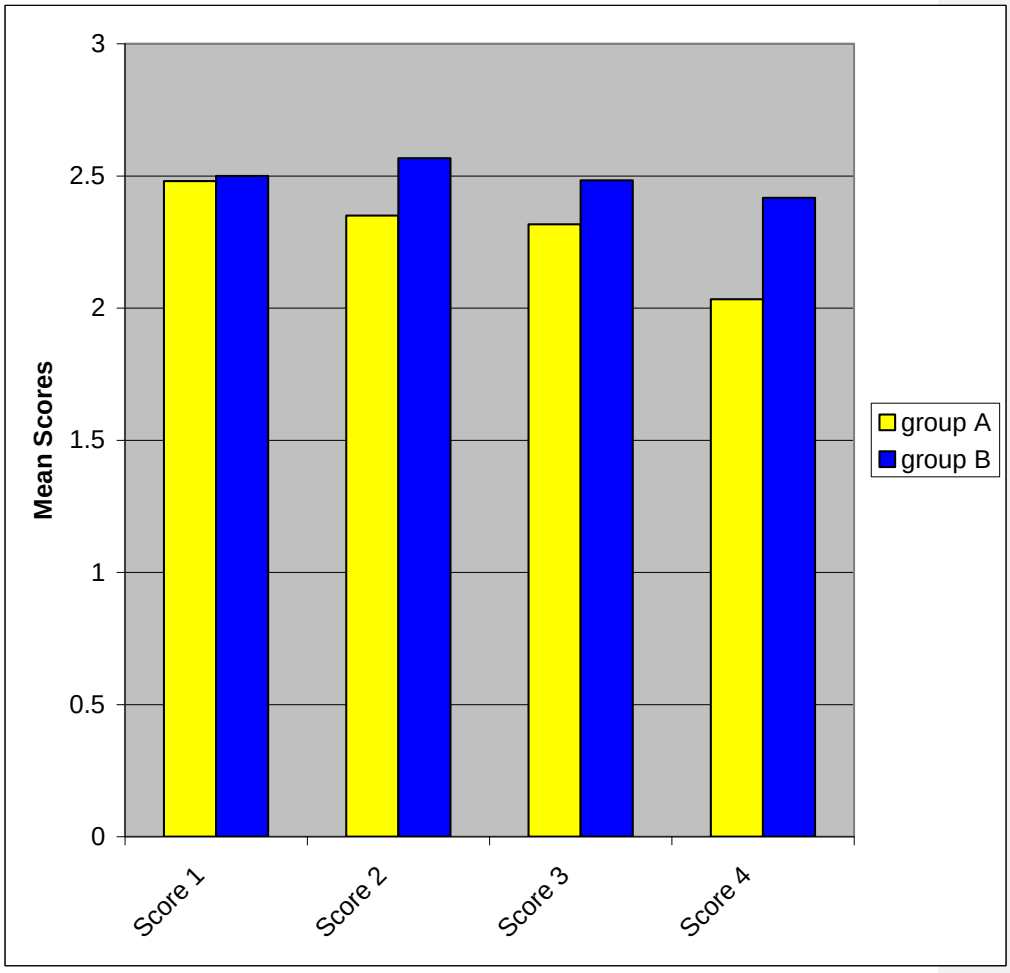


FIGURE 4.9

BAR CHART COMPARING THE MEAN TOTAL SCORES OF GROUP A (ADVANCED BRAIN FOOD®) AND GROUP B (QUIETUDE®) FOR HYPERACTVITY



4.4.1 INTRA-GROUP ANALYSIS: FRIEDMAN'S TEST

The Friedman's test was used to test for the presence of significant differences between the four consultations in each group. At the $\alpha = 0.05$ level of significance, the test revealed that there was no statistically significant difference for the Inattention, Hyperactivity and Impulsivity or the Total Scores between the consultations of the two groups compared ($p > 0.05$ - the null hypothesis H_0 is accepted).

TABLE 4.6

INTRA-GROUP COMPARISON OF THE DATA FOR GROUP A (ADVANCED BRAIN FOOD®) USING FRIEDMAN'S TEST

SCORES	P-VALUE	CONCLUSION
CONDUCT PROBLEMS	0.098	NO DIFFERENCE
INATTENTION	0.110	NO DIFFERENCE
PSYCHOSOMATIC PROBLEMS	0.690	NO DIFFERENCE
IMPULSIVITY	0.174	NO DIFFERENCE
ANXIETY	0.884	NO DIFFERENCE
HYPERACTIVITY	0.087	NO DIFFERENCE

TABLE 4.7

INTRA-GROUP COMPARISON OF THE DATA FOR GROUP B (QUIETUDE ®) USING FRIEDMAN'S TEST

SCORES	P-VALUE	CONCLUSION
CONDUCT PROBLEMS	0.871	NO DIFFERENCE
INATTENTION	0.377	NO DIFFERENCE
PSYCHOSOMATIC PROBLEMS	0.482	NO DIFFERENCE
IMPULSIVITY	0.117	NO DIFFERENCE
ANXIETY	0.143	NO DIFFERENCE
HYPERACTIVITY	0.758	NO DIFFERENCE

Conclusion

For all test categories (Conduct Problems, Inattention, Psychosomatic Problems, Impulsivity, Anxiety, Hyperactivity) the results obtained from the Friedman's Test indicated that there was no statistical difference between results obtained between Group A (Advanced Brain Food®) and Group B (Quietude®) subjects during the four assessments periods

4.4.2 INTER-GROUP ANALYSIS: MANN WHITNEY TEST

Mann Whitney U-Test

Mann Whitney U test was used to examine significant differences between group A and group B subjects in their assessment scores at the four different assessment periods.

At the $\alpha = 0.05$ level of significance, there was no statistically significant difference for~~;~~ the Inattention scores on all four questionnaires; the Anxiety scores on all four questionnaires; the Hyperactivity scores for questionnaires 1,2,3,4. ($P > 0.05$ – the null hypothesis H_0 is accepted). There were however significant statistical differences noted for Conduct Problems at Questionnaire 3, Psychosomatic Problems at Questionnaire 1, 3 and 4, Impulsivity at Questionnaire 3.

Score 1 value (baseline) for group A (mean score=1.475) and B (mean score=2.37) were significantly different to begin with i.e. the two groups were not comparable initially regarding psychosomatic problems.

TABLE 4.8

INTER-GROUP COMPARISON OF THE DATA FOR CONDUCT PROBLEMS

TESTS	Score 1	Score 2	Score3	Score 4
Mann-Whitney U	50.000	38.000	20.000	36.500
Asymp. Sig. (2-tailed)	1.000	0.361	**0.023**	0.302
Exact Sig. [2*(1-tailed Sig.)]	1.000	0.393	**0.023**	0.315

At the $\alpha = 0.05$ level of significance the test revealed that there was a statistically significant difference for the Conduct Problems scores on questionnaires 3($p < 0.05$ – the null hypothesis H_0 is rejected) (P=0.023). For all other intervals H_0 is accepted i.e. no significant differences was seen.

TABLE 4.9

INTER-GROUP COMPARISON OF THE DATA FOR INATTENTION

Tests	Score 1	Score 2	Score3	Score 4
Mann-Whitney U	44.000	34.500	31.500	35.500
Asymp. Sig. (2-tailed)	0.649	0.238	0.159	0.265
Exact Sig. [2*(1-tailed Sig.)]	0.684	0.247	0.165	0.280

At the $\alpha = 0.05$ level of significance the test revealed that there was no statistically significant difference seen for the category Inattention. For all other intervals H_0 is accepted.

TABLE 4.10

INTER-GROUP COMPARISON OF THE DATA FOR PSYCHOSOMATIC PROBLEMS

Tests	Score 1	Score 2	Score3	Score 4
Mann-Whitney U	19.000	24.000	13.000	17.000
Asymp. Sig. (2-tailed)	0.018	0.048	0.005	0.012
Exact Sig. [2*(1-tailed Sig.)]	**0.019**	0.052	**0.004**	**0.011**

At the $\alpha = 0.05$ level of significance the test revealed that there was a statistically significant difference for the Psychosomatic Problems scores on questionnaires 1 ($p=0.019$), 3 ($p=0.004$) and 4 ($p=0.011$). $p < 0.05$ – the null hypothesis H_0 is rejected Although $p < 0.05$ it can be argued that due to an initial difference at the baseline in mean scores obtained between the two group for Psychosomatic Problems, it seems that Group A (Advanced Brain Food®) had an advantage over Group B (Quietude®), thus H_0 is accepted.

TABLE 4.11

INTER-GROUP COMPARISON OF THE DATA FOR IMPULSIVITY

Tests	Score 1	Score 2	Score3	Score 4
Mann-Whitney U	34.000	42.000	22.500	29.000
Asymp. Sig. (2-tailed)	0.212	0.536	0.036	0.106
Exact Sig. [2*(1-tailed Sig.)]	0.247	0.579	**0.035**	0.123

At the $\alpha = 0.05$ level of significance the test revealed that there was a statistically significant difference for the Impulsivity scores on questionnaires 3. ($p < 0.05$ – the null hypothesis H_0 is rejected) (P=0.035). For all other intervals H_0 is accepted i.e. no significant differences is seen.

TABLE 4.12

INTER-GROUP COMPARISON OF THE DATA FOR ANXIETY

Tests	Score 1	Score 2	Score3	Score 4
Mann-Whitney U	31.000	40.000	39.500	42.000
Asymp. Sig. (2-tailed)	0.144	0.445	0.418	0.543
Exact Sig. [2*(1-tailed Sig.)]	0.165	0.481	0.436	0.579

At the $\alpha = 0.05$ level of significance the test revealed that there was no statistically significant difference seen for the category Anxiety For all other intervals H_0 is accepted.

TABLE 4.13

INTER-GROUP COMPARISON OF THE DATA FOR HYPERACTIVITY

Tests	Score 1	Score 2	Score3	Score 4
Mann-Whitney U	47.000	34.000	41.000	35.000
Asymp. Sig. (2-tailed)	0.819	0.219	0.490	0.252
Exact Sig. [2*(1-tailed Sig.)]	0.853	0.247	0.529	0.280

TABLE 4.14

SUMMARY OF TOTAL MEAN RANKS FOR THE SBL SCORES

	Group A (Advanced Brain Food®)				Group B (Quietude®)			
	Score 1	Score 2	Score 3	Score 4	Score 1	Score 2	Score 3	Score 4
Conduct Problems	2.85	3	1.75	2.4	2.4	2.25	2.75	2.3
Inattention	3.15	2.4	2.25	1.9	2.35	2.2	3.1	2.35
Psychosomatic Problems	1.46	1.43	1.45	1.3	2.37	2.17	2.5	2.2
Impulsivity	2.8	2.95	2.25	2	2	2.1	2.95	2.95
Anxiety	2.25	2.65	2.5	2.6	3.05	2.65	2.5	1.8
Hyperactivity	3.05	2.65	2.6	1.7	2.85	2.45	2.4	2.3

Score 1 value (baseline) for group A (mean score=1.475) and B (mean score=2.37) were significantly different to begin with i.e. the two groups were not comparable initially regarding psychosomatic problems.

4.5 RESULTS OF THE CHILDREN CHECKING TASK (APPENDIX J2-J5)

Test results (raw data) for each subject that participated in the trial are available in the appendices mentioned below. The CCT results were made up of three tests. The first administered before treatment commenced, the second three weeks and the third six ~~6~~ weeks after the treatment period. Group A (Advanced Brain Food®) and group B (Quietude®) group each consisted of 10 subjects (n=10). Results were converted into percentages, higher marks indicating better results. The CCT results were~~as~~ categori~~s~~z~~e~~d into four groups:

- Total scores for letters
- Total scores for numbers
- Total scores for symbols
- Total scores for words.

Test results for each group can be found in the appendices. An improvement in the overall test results would indicate an increase in sustained attention level (Strauss, 2000).

REFRENCE KEY FOR FIGURES

BASELINE	Test before medication was given
TEST 2	Test done after three~~3~~ weeks
TEST 3	Test done after six~~6~~ weeks
GROUP A	Advanced Brain Food®
GROUP B	Quietude®

FIGURE 4.10

BAR CHART COMPARING All SCORES OBTAINED FOR CCT 1(Letters)

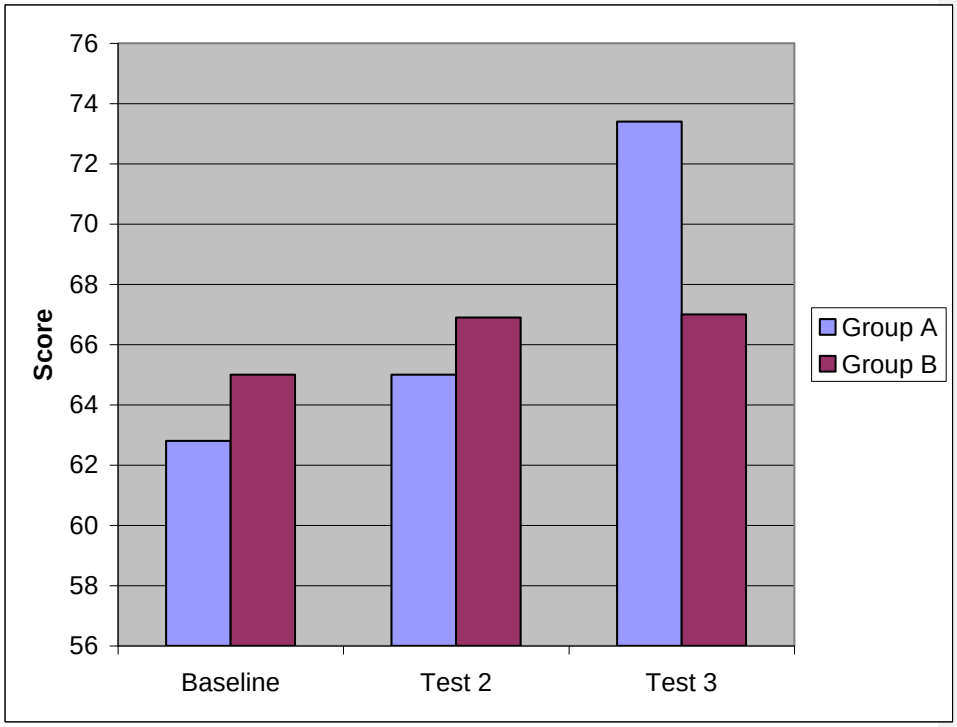


FIGURE 4.11

BAR CHART COMPARING ALL SCORES OBTAINED FOR CCT 2 (Numbers)

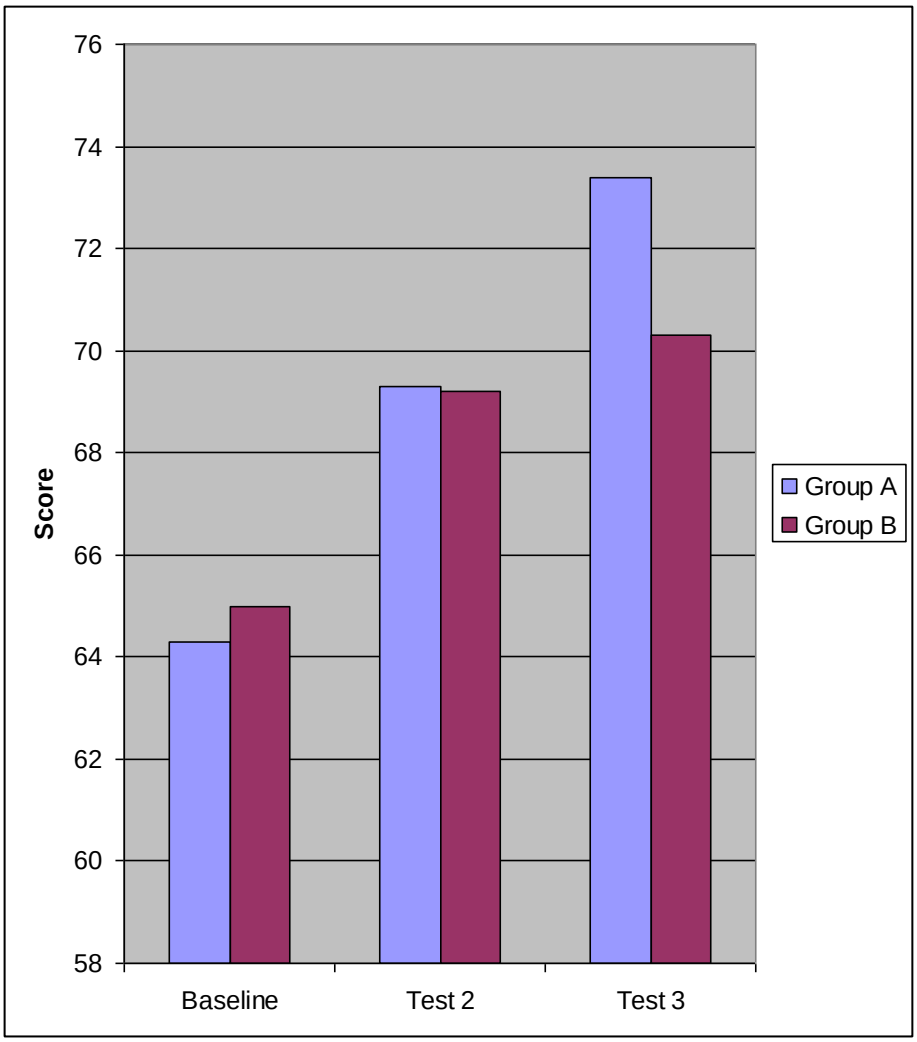


FIGURE 4.12

BAR CHART COMPARING SCORES OBTAINED FOR CCT 3 (Symbols)

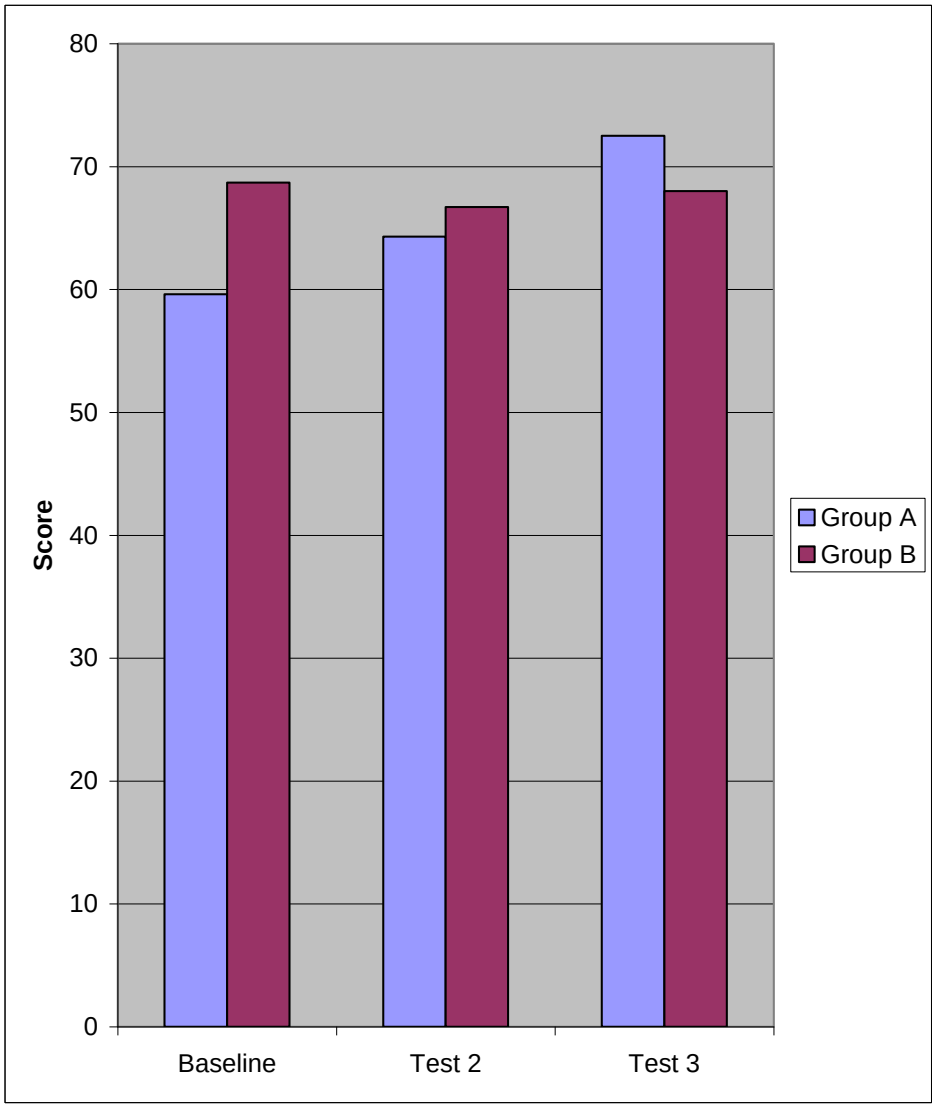
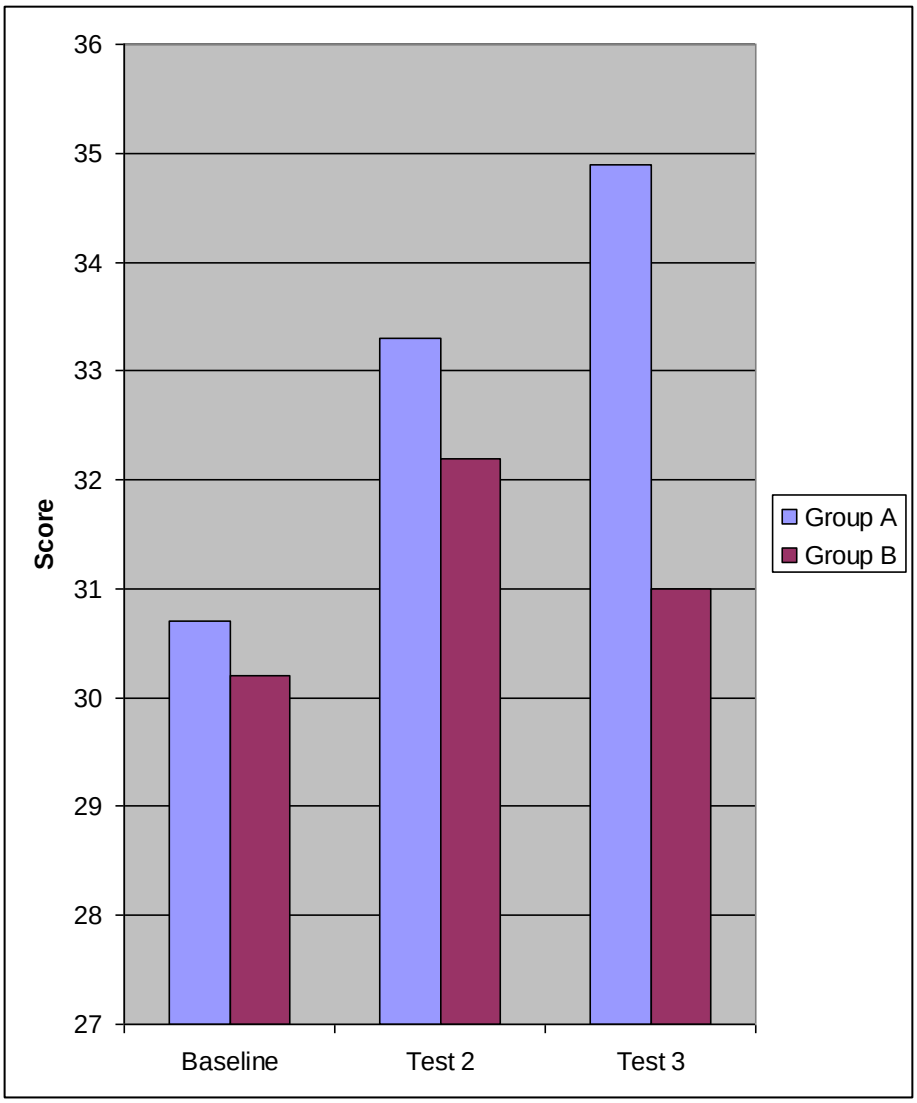


FIGURE 4.13

BAR CHART COMPARING SCORES OBTAINED FOR CCT 4 (Words)



4.5.1(A) INTRA-GROUP ANALYSIS: FRIEDMAN'S TEST

The Friedman's test was used to test for the presence of significant differences between the three consultations in each group.

TABLE 4.15

INTRA-GROUP COMPARISON OF THE DATA FOR GROUP A (ADVANCED BRAIN FOOD®) USING FRIEDMAN'S TEST

SCORES	P-VALUE	CONCLUSION
CCT 1 (LETTERS)	**0.001**	DIFFERENCE
CCT 2 (NUMBERS)	**0.007**	DIFFERENCE
CCT 3 (SYMBOLS)	**0.001**	DIFFERENCE
CCT 4 (WORDS)	0.139	NO DIFFERENCE

TABLE 4.16

INTRA-GROUP COMPARISON OF THE DATA FOR GROUP B (QUIETUDE®) USING FRIEDMAN'S TEST

SCORES	P-VALUE	CONCLUSION
CCT 1 (LETTERS)	0.590	NO DIFFERENCE
CCT 2 (NUMBERS)	1.00	NO DIFFERENCE
CCT 3 (SYMBOLS)	0.214	NO DIFFERENCE
CCT 4 (WORDS)	0.273	NO DIFFERENCE

4.5.1(B) INTRA-GROUP ANALYSIS: WILCOXON'S TEST

TABLE 4.17

INTRA-GROUP COMPARISON OF THE DATA FOR THE CHILDREN'S CHECKING TASK FOR GROUP A USING WILCOXON'S TEST

	TEST 1	TEST 2	TEST 3
CCT 1 (Letters) 2 Tailed p-value	0.0556	**0.0020**	**0.0020**
CCT 2 (Numbers) 2 Tailed p-value	0.0109	0.013	**0.005**
CCT 3 (Symbols) 2 Tailed p-value	0.0492	**0.002**	**0.002**
CCT 4 (Words) 2 Tailed p-value	0.0431	0.0128	0.0164

CONCLUSION (INTRA-GROUP ANALYSIS)

GROUP A

CCT 1 (LETTERS)

At the $\alpha = 0.05$ level of significance, the test revealed that there was a statistically significant difference **(p=0.001)** for CCT 1 (letters) between the three consultations for Group A (Advanced Brain Food®). The Wilcoxon's test revealed a statistical significant difference between test 1 (baseline) and test 2 **(p=0.02)** and between test 1(baseline) and test 3**(p=0.02).** $p < 0.05$ - thus H_1 is accepted

CCT2 (WORDS)

At the $\alpha = 0.05$ level of significance, the test revealed that there was a statistically significant difference **(p=0.007)** for CCT 2 (Numbers) between the three consultations for Group A (Advanced Brain Food®) The Wilcoxon's test revealed a statistical significant difference between test 1 (baseline) and test 3 **(p=0.059)**.($p < 0.05$ -thus H_1 is accepted).

CCT 3 (SYMBOLS)

At the $\alpha = 0.05$ level of significance, the test revealed that there was a statistically significant difference **(p=0.001)** for CCT 3 (Symbols) between the three consultations for Group A (Advanced Brain Food®).The Wilcoxon's test revealed a statistical significant difference between test 1 (baseline) and test 2 **(p=0.02)** and between test 1(baseline) and test 3**(p=0.02).** ($p < 0.05$ thus H_1 is accepted).

CCT 4 (WORDS)

At the $\alpha = 0.05$ level of significance, there was no statistically significant difference for, CCT 4 (Words) on all three questionnaires in Group A. ($p > 0.05$ – the null hypothesis H_0 is accepted)

GROUP B

The results from the Friedman's Test for CCT 1, CCT 2, CCT 3, and CCT 4 revealed no statistical difference for results obtained during the three assessment periods ($p > 0.05$ the null hypothesis H_0 is accepted).

4.5.2 INTER-GROUP ANALYSIS: MANN WHITNEY U-TEST

Mann Whitney U test was used to examine significant differences between group A (Advanced Brain Food®) and group B (Quietude®) subjects in their assessment scores at the three different assessment periods

TABLE 4.18

INTER-GROUP COMPARISON OF THE DATA FOR CCT 1 (Letters)

TESTS	Score 1	Score 2	Score3
Mann Whitney U Test	43.000	44.000	18.000
Asymp. Sig. (2-tailed)	0.596	0.648	**0.015**
Exact Sig. [2*(1-tailed Sig.)]	0.631	0.684	**0.015**

At the $\alpha = 0.05$ level of significance, the test revealed that there was no statistically significant difference between Score 1, Score 2 ($p > 0.05$ – the null hypothesis H_0 is accepted). There was however a significant statistical difference at Score 3 ($p<0.05$ – H_1 is accepted).

TABLE 4.19

INTER-GROUP COMPARISON OF THE DATA FOR CCT 2 (Numbers)

Tests	Score 1	Score 2	Score3
Mann-Whitney U	42.000	45.000	24.500
Asymp. Sig. (2-tailed)	0.545	0.703	0.050
Exact Sig. [2*(1-tailed Sig.)]	0.579	0.739	0.052

At the $\alpha = 0.05$ level of significance, the test revealed that there was no statistically significant difference between Score 1, Score 2 and Score 3 ($p > 0.05$ – H_0 is accepted).

TABLE 4.20

INTER-GROUP COMPARISON OF THE DATA FOR CCT 3 (Symbols)

Tests	Score 1	Score 2	Score3
Mann-Whitney U	26.000	40.000	19.000
Asymp. Sig. (2-Tailed)	0.069	0.448	**0.019**
Exact Sig. [2*(1-tailed Sig.)]	0.075	0.481	**0.019**

At the $\alpha = 0.05$ level of significance, the test revealed that there was no statistically significant difference between Score 1and Score 2 ($p > 0.05$ – the null hypothesis H_0 is accepted). There was however a significant statistical difference at Score 3 ($p<0.05$ – H_1 is accepted).

TABLE 4.21

INTER-GROUP COMPARISON OF THE DATA FOR CCT 4 (Words)

Tests	Score 1	Score 2	Score3
Mann-Whitney U	46.500	43.000	26.500
Asymp. Sig. (2-Tailed)	0.790	0.594	0.073
Exact Sig. [2*(1-tailed Sig.)]	0.796	0.631	0.075

At the $\alpha = 0.05$ level of significance, the test revealed that there was no statistically significant difference between Score 1, Score 2 and Score 3 ($p > 0.05 – H_0$ is accepted).

TABLE 4.22

SUMMARY OF TOTAL MEAN RANKS OF SCORES OBTAINED FOR THE CHILDREN'S CHECKING TASK (CCT)

	GROUP A ADVANCED BRAIN FOOD®			GROUP B QUIETUDE®		
	Score 1	**Score 2**	**Score 3**	**Score 1**	**Score 2**	**Score 3**
CCT 1 (Letters)	1.5	1.5	3	2.1	1.75	2.15
CCT 2 (Numbers)	1.35	1.95	2.7	2	2	2
CCT 3 (Symbols)	1.4	1.6	3	2.35	1.6	2.05
CCT 4 (Words)	1.75	1.75	2.5	1.9	2.4	1.7

4.5.3 SUMMARY OF SCORES OBTAINED FOR THE CHILDREN'S CHECKING TASK DURING THE THREE OBSERVATIONS

TABLE 4.23

Summary of Results for CCT 1 (Letters) for the two groups

	Advanced Brain Food® (N=10)			Quietude® (N=10)		
	Baseline	Test 2	Test 3	Baseline	Test 2	Test 3
Mean Scores	62.8	65	73.4	65	66.9	67
Std. Deviation	10.539	7.196	4.402	8.042	5.280	5.121
Minimum	38	50	65	45	60	57
Maximum	74	75	78	72	74	75

Group A (Advanced Brain Food®) showed a 10.6% overall improvement in mean test scores obtained for CCT1. Group B (Quietude®) showed a 2% overall improvement in mean test scores obtained for CCT 1. Group A performed 8.6% better for CCT1 than group B subjects.

TABLE 4.24

Summary of Results for CCT 2 (Numbers) for the two groups

	Advanced Brain Food® (N=10)			Quietude® (N=10)		
	Baseline	Test 2	Test 3	Baseline	Test 2	Test 3
Mean Score	64.3	69.3	73.4	65	69.2	70.3
Std. Deviation	10.54	4.06	2.41	12.68	6.83	3.60
Minimum	49	62	70	32	58	64
Maximum	75	75	78	75	77	76

Group A (Advanced Brain Food®) showed a 9.1% overall improvement in mean test scores obtained for CCT2. Group B (Quietude®) showed a 5.3% overall improvement in mean test scores obtained for CCT 2. Group A performed 3.8% better for CCT2 than group B subjects.

TABLE 4.25

Summary of Results for CCT 3 (Symbols) for the two groups

	Advanced Brain Food® (N=10)			Quietude® (N=10)		
	Baseline	Test 2	Test 3	Baseline	Test 2	Test 3
Mean Scores	59.6	64.3	72.5	68.7	66.7	68
Std. Deviation	14.191	7.119	4.403	5.618	5.314	4.320
Minimum	25	49	62	60	56	59
Maximum	73	74	77	76	73	74

Group A (Advanced Brain Food®) showed a 12.9% overall improvement in mean test scores obtained for CCT3. Group B (Quietude®) showed a 0.7% regression in mean test scores obtained for CCT 3. Group A performed 13.6% better for CCT3 than group B subjects.

Table 4.26

Summary of Results for CCT 4 (Words) for the two groups

	Advanced Brain Food® (N=10)			Quietude® (N=10)		
	Baseline	Test 2	Test 3	Baseline	Test 2	Test 3
Mean Scores	30.7	33.3	34.9	30.2	32.2	31
Std. Deviation	6.343	3.401	4.202	6.321	3.645	3.651
Minimum	14	28	29	17	24	23
Maximum	36	38	40	37	36	35

Group A (Advanced Brain Food®) showed a 4.2% overall improvement in mean test scores obtained for CCT4. Group B (Quietude®) showed a 0.8% overall improvement in mean test scores obtained for CCT 4. Group A performed 3.4% better for CCT4 than group B subjects.

Conclusion (Children's Checking Task) - INTER-GROUP COMPARISON

Group A: An overall improvement of 36.8 % (Percentage improvement of CCT1 + CCT2 + CCT3 +CCT4) was seen in results obtained for the Children's Checking Task.

Group B: An overall improvement of 7.4 % (Percentage improvement of CCT1 + CCT2 + CCT3 +CCT4) was seen in results obtained for the Children's Checking Task.

CHAPTER 5

DISCUSSION

Attention deficit hyperactivity disorder (ADHD) is the most commonly diagnosed behavioural disorder of childhood, estimated to affect three~~3~~ to five~~5~~ percent of school-age children. Its core symptoms include a developmentally inappropriate level of attention and concentration, developmentally inappropriate levels of activity, distractibility, and impulsivity (NIH Consensus Statement, 1999). Children with ADHD usually have pronounced difficulties and impairment resulting from the disorder across multiple settings in home, at school, and with peers as well as resultant long-term adverse effects on later academic, vocational, social-emotional, and psychiatric outcomes (Holford, 2001).

Despite the progress in the assessment, diagnosis, and treatment of children and adults with ADHD, the disorder has remained controversial in many public and private sectors (Greenhill et al. 1992). The confusion resulting from diverse, frequently expressed opinions has made many families, health care providers, educators, and policymakers uncertain about the status of the disorder and its long-term consequences, whether it should be treated, and, if so, how (NIH Consensus Statement, 1999).

Diagnoses are often made in an inconsistent manner with children sometimes being over-~~–~~diagnosed and sometimes being under-~~–~~diagnosed. Some practitioners do not use structured parent questionnaires or rating scales or teacher or school input (NIH Consensus Statement, 1999; Strauss, 2000).

Paediatricians, family practitioners, and psychiatrists tend to rely on parent rather than teacher input (Holford, 2001; Strauss, 2000). There appears to be a "disconnect" between developmental or educational (school-based) assessments and health- related (medical practice-based) services. There is often poor communication between diagnosticians and those who implement and monitor treatment in schools (Baizear, 2001).

One of the major controversies regarding ADHD concerns the use of psychostimulants to treat the condition (Karen et al. 1997). Psychostimulants, including amphetamine, methylphenidate, and Pemoline®, are by far the most widely researched and commonly prescribed treatments for ADHD (Breggin, 1999; NIH Consensus Statement, 1999). The use of methylphenidate and amphetamine nationwide has increased significantly in recent years. The increased production and use of psychostimulants have intensified the concerns about use, overuse, and abuse (Green and Chee, 1997; NIH Consensus Statement, 1999; O'Shea, 2000).

Ritalin® does not make a difference in the long-term outcome of ADD/ADHD. A recent study carried out at Montreal Children's Hospital discovered that at the end of five years, hyper-kinetic children who received stimulant drugs (Ritalin® or Chlorpromazine®) did not differ significantly from children who had not received these drugs (Holford, 2001). Although it appeared that hyperactive children treated with Ritalin® were initially more manageable, the degree of improvement and emotional adjustment was essentially identical at the end of five years to that seen in a group of children who had received no medication at all.

Another factor to consider is that stimulant medication has some further limitations such as side effects ranging from loss of appetite to depression and, there is often a rebound effect or worsening of symptoms as medication wears off (Middleborough, 2001). Parents/guardians in this study were hesitant to administer the medication to their children because of a major sedating effect it had on them (Strauss, 2000; Personal Communication with the ADHD Support Group of South Africa, 2003). In some instances, this stimulant medication just does not work (Breggin, 1999; Holford, 2000). The National Institute of Health concluded that there is no evidence of any long-term improvement in scholastic performance by the use of stimulant drugs (NIH Consensus Statement, 1999).

Although most parents prefer non-pharmacological interventions for the treatment of ADHD, there is not sufficient information about alternative modes of treatments available to them (Breggin, 1999). It can only be assumed that a large percentage of children being treated in the community are not being given the option of non-pharmacological treatments, given that 80% of children are treated by stimulant medications, and less than a third having non-pharmacological supports (Holford, 2002).

Nutritional treatment has proven very helpful for many hyperactive children and has few, if any, side- effects (Holford, 2002). Many parents do not have the finances available to pay for nutritional supplementation and these are more often than not readily available, particularly in rural areas (Strauss, 2000). Research has shown that while behavioural interventions are often extremely successful their success tends to be restricted to the context for which they were developed (Breggin, 2000).

Schools, which cater for children with learning disabilities, often employ these behavioural interventions. The problem is that these types of schools are in short supply and often have waiting lists of three or more years. These behavioural management programmes are of the most benefit to the younger children. After the age of ten children show a natural resistance to external structuring and control which negates the effectiveness of these programmes (Breggin, 1999).

The effect of vitamin and mineral supplements on academic performance and children's behavioural problems is well documented (Holford, 2002). It currently seems unlikely that ADHD is caused solely by nutrient deficiencies but addressing such deficiencies can significantly improve ADHD symptoms (Holford, 2002). Children with ADHD more often than not have one or more nutritional imbalances that, once identified and corrected, can dramatically improve their energy, focus, concentration and behaviour (Holford, 2000).

Advanced Brain Food® is a nutritional supplement that consists of a combination of vitamins and essential nutrients. The main aim of this nutritional formulation is to assist with nutritional imbalances that a person might have and in doing so, it may assist in correcting neurotransmitter imbalances that may be present in the brain of an ADHD child (Holford, 2001).

Alternatives like supplementation and homoeopathy is not new, but the amount of exposure they receive and the research into their effectivity is minimal when compared with mainstream treatments like Ritalin® (Middleborough, 2001).

Homoeopathically prepared Quietude® has never been tested for the management of ADHD. Quietude® ~~it~~ is deemed safe with no side ~~-~~effects and its effectiveness in the management of ADHD is unknown. All the constituents of Quietude® have, to a greater or lesser degree, symptoms that correlate with the symptoms of ADHD. The reason for administering Quietude® in a homoeopathically prepared form was derived from homotoxocological methods, which aim to correlate pathological symptoms with similar remedy symptom presentations. This method makes use of diluted levels of chemicals or compounds prepared in a "homoeopathic-like" manner in order to correct imbalances in the body. The rationale behind this approach is that simple dilutions of chemicals or compounds do not have the necessary concentration of ingredients to correct deficiencies in the body. The remedies that were prepared in a homoeopathic manner using succussion, were not acting on a physical level, but on an energetic level that stimulates the body's innate abilities to correct its own deficiencies.

The researcher chose 20 school going boys between the ages of eight~~8~~ and 13 years. The reason for choosing only boys was that the incidence of ADHD is significantly higher in boys than girls (NIH Consensus Statement, 1998). This condition however, is more often than not under-identified in girls (Berkow et al. 1992). This chapter attempts to explain the results of the statistical analysis on the efficacy of Advanced Brain Food® and Quietude® for the use as an alternative treatment for ADHD.

STATISTICAL ANALYSIS

When the study was first proposed, it was intended to have a sample size of thirty and therefore a group size of fifteen. Although many parents volunteered their children for the research, relatively few were willing or able to cease their child's current treatment. Some of the factors that influenced the recruiting of the subjects and their compliance to the research involved the following:

- Many parents who initially intended ~~in~~to participat~~e~~ing in the trial were concerned about ceasing current treatment regimes for a period of six weeks. Research done by Middleborough (2001) encountered the same problem.
- Patient compliance was poor during the trial and this accounted for some subjects being~~to be~~ excluded from the research (Middleborough, 2001; Strauss, 2000).
- The pharmaceutical company that manufactures Ritalin® had expressed concerns about the ethical aspects of the research and thus warned relevant medical personnel about the research project and encouraged them to discourage potential patients from partaking in the clinical trail. This hampered canvassing of subjects to a great extent.
- Many schools did not want to give approval for the trial as they felt that even a study of six weeks could affect the overall performance of the child (Middleborough, 2001).
- Some participants had to be eliminated from the study after parents were unable to comply with the treatment regime of two doses per day at regular intervals.

- Obtaining a clinical assessment diagnosing a child as having ADD/ADHD is a time consuming and relatively expensive procedure.
- Not all subjects who are diagnosed as having ADD/ADHD are assessed via the DSM-V criteria and the diagnosis is often made by only a general practitioner (Middleborough, 2001; Strauss, 2000).
- Not all parents have the time to monitor their child's progress because they work most of the day and quite often leave the child at a day care centre after school.
- Many lower income families are not aware or educated on issues like ADD/ADHD and so parents are more likely to think they have a troublesome child than a child with a learning disability. In addition, the schools that these children attend are sometimes lacking in basic facilities like a school psychologist who could usually identify learning disorders as they present (Middleborough, 2001).
- Of the initial 30 participants selected, only 20 participants completed the clinical trial. This was due to the limited time available (to the researcher) to conduct the clinical trial, patient compliancy during the clinical trial and schools of the potential participants who did not want to allow a period of six~~6~~ weeks due to a fear of disruption in school activities.

ADHD Rating Scale

Baseline measurements of group A (Advanced Brain Food®) and group B (Quietude®) for inattention, hyperactivity/ impulsivity and total scores did not differ statistically. As has been discussed previously, children with ADHD may be predominantly inattentive,

predominantly hyperactive/impulsive or a combination of the two. The ADHD Rating scale measured the degree of inattention and hyperactivity/impulsivity that the subjects may experience. The actual mean scores reflected that there was no statistical difference between the two groups.

INTRA-GROUP FINDINGS FOR GROUP A

No statistically significant difference was noted for inattention, hyperactivity/impulsivity component nor was there a statistically significant difference for the total score in all measurements for group A (Advanced Brain Food®). The p-value for all four assessments was greater than 0.05.

Symptoms of inattention, hyperactivity/impulsivity did not improve significantly over the three assessment periods measured for the group taking Advanced Brain Food®.

INTRA-GROUP FINDINGS FOR GROUP B

No statistically significant difference was noted for inattention, hyperactivity/impulsivity component nor was there a statistically significant difference for the total score in all measurement for group B(Quietude®). The p-value for all four assessments was greater than 0.05.

Symptoms of inattention, hyperactivity/impulsivity did not improve significantly over the three assessment periods measured for the group taking Quietude®.

INTER-GROUP FINDINGS FOR GROUP A AND GROUP B

No statistically significant difference was noted for inattention, hyperactivity/impulsivity component nor was there a statistically significant difference for the total score in all measurements between group A (Advanced Brain Food®) and group B (Quietude®). The p-value for all four assessments was greater than 0.05.

CONCLUSION

It can be concluded that the administration of Advanced Brain Food® and Quietude® did not result in any significant changes in the respective groups as measured by the ADHD rating scale i.e. hyperactivity and impulsivity.

POSSIBLE EXPLANATIONS FOR THE RESULTS OBTAINED FOR THE ADHD RATING SCALE

The symptoms that are rated in the questionnaire can be influenced by external factors, which are separate from the child's condition: work load at school varies from week to week, which~~this~~ can lead to fluctuation in the child's behaviour and performance; the parents' mood and attitude can be influenced by work-load and relationships;~~,~~ these factors can influence the way in which they perceive their child's behaviour and so influence the scores they give to the child's symptoms (Middleborough, 2001).

Parents/guardians who completed these questionnaires often felt that some of the questions that had to be answered were irrelevant to their child's condition and ultimately

just circled an answer for the sake of completion for the questionnaire. This might account for no statistical difference in the results.

As mentioned earlier, there is no specific test/evaluation that completely encompasses the diversity of symptoms with which ~~that~~ a child with ADHD might present ~~with~~. The ADHD scale was originally designed for research purposes or for evaluations done by medical professionals. In this study the inconclusive results seen might indicate that the ADHD Rating Scale (home version) should be replaced with the ADHD Rating Scale (school version) if such a study is attempted in the future. For an accurate reflection of symptoms, a medical professional will need to obtain information about the child directly from the classroom teacher or another school professional, which ~~that~~ was not the case in this study. Another possible explanation for the results obtained could be due to the time period/frequency of assessments done.

Children who were accepted into the study had to have been previously diagnosed by a medical practitioner. As has been pointed out previously not all medical practitioners take the time to analyse and assess the child sufficiently before diagnosing ADD/ ADHD. Due to budget constraints, children could not be referred for individual psychological assessment. For this reason some of the children who were entered into the study may well have been misdiagnosed. ADD/ADHD is a dynamic disorder with many different factors influencing a child's behaviour (Middleborough, 2001). Psychological intervention may be necessary in those children whose problems stem from psychosomatic factors like relationships.

Student Bbehaviour Log (SBL)

This questionnaire examined the following aspects of the subjects: Verbal-linguistic, Logical-mathematical, Visual spatial, Body-kinaestetickinaesthetic, Musical-rythmicalrhythmical, Interpersonal and nNaturalist behaviours (Strauss, 2000). It is a useful assessment technique for parents/teachers that have an ADHD child. The SBL results have been divided up into their respective categories and will be discussed in terms of intra-group and inter-group comparisons below. The Hyperactivity Index is the overall measure of hyperactivity, taking into account typical ADHD symptoms. The remaining five categories are measures of single common problems typically seen in ADHD.

INTRA-GROUP FINDINGS FOR GROUP A AND GROUP B

The Friedman's test was used in this analysis. For all test categories (Conduct Problems, Inattention, Psychosomatic Problems, Impulsivity, Hyperactivity) the results indicated that there was no statistically differences in the results obtained from Group A (Advanced Brain Food®) and Group B (Quietude®) during the four assessment periods.

The category of Psychosomatic Problems on the SBL is primarily used to monitor side effects to stimulant medication (Strauss, 2000). As a prerequisite for the research, participants were not allowed to take any orthodox medication for ADHD during the trial period.

Initial examination of the results reveal that Group A (Advanced Brain Food®) had a substantial improvement when compared to group B (Quietude®) with regards to the category Psychosomatic Problems.

If one further examine these results, it becomes apparent that Group A (Advanced Brain Food®) had a mean score of 1.475 at assessment 1 i.e. baseline score. Group B (Quietude®) had a mean score 2.37(baseline score). It can be concluded that the two groups were not completely homogenous from the start of the study with reference to the test category Psychosomatic Problems in the Student Behaviour Log (SBL). For some reason Group A (Advanced Brain Food®) had an advantage over Group B (Quietude®). The~~se~~ results obtained can~~-~~not be used to conclude that Group A performed better than Group B during the four assessment periods.

As mentioned earlier symptoms that are rated in the questionnaire can be influenced by external factors, which are separate from the child's condition: workload at school varies from week to week which ~~, this~~ can lead to fluctuation in the child's behaviour and performance; the parents' mood and attitude can be influenced by work~~-~~load and relationships. This can attribute to the statistical difference or advantage of Group A over Group B subjects seen in the test category (Psychosomatic Problems) for the Student Behaviour Log.

Other test categories for the Student Behaviour Log (SBL) revealed no statistical difference between group A (Advanced Brain Food®) and Group B (Quietude®) subjects throughout the study.

Neither intervention resulted in any intra-group changes throughout the study. Thus, according to the ~~Student Behaviour Log (~~SBL~~)~~, behaviour remained fairly constant throughout the study.

INTER-GROUP FINDINGS FOR GROUP A (Advanced Brain Food®) AND GROUP B (Quietude®)

The Mann Whitney U-test was used to examine significant differences between group A and group B in their assessment scores at the four different assessment periods.

For test categories: Inattention, Anxiety and Hyperactivity

Results revealed that no statistical differences existed between group A (Advanced Brain Food®) and group B(Quietude®) at the four different assessment periods for the abovementioned test categories.

For test category: Conduct Problems

Results revealed that no statistical difference existed between group A (Advanced Brain Food®) and group B (Quietude®) for assessment period 1, 2 and 4. In all cases the p-value was greater than 0.05. At assessment period 3 a statistical significant difference was seen between group A and B (P-value = 0.023).

The Conduct Problem's category of the SBL, evaluates symptoms such as disobedience, destructiveness, rebelliousness, and disrespect towards elders (Strauss, 2000). The

statistical difference seen in group A (Advanced Brain Food®) can be attributed to the child's general mood and behaviours at home or the parents' general mood or behaviours at home at the time that the assessment was done.

For test category: Impulsivity

Results revealed that no statistical differences existed between group A (Advanced Brain Food®) and group B (Quietude®) for assessment periods 1, 2 and 4. In all cases the p-value was greater than 0.05. At assessment period 3 a statistically significant difference was noted between group A and group B (p-value = 0.035).

For test category: Psychosomatic Problems

Results revealed that no statistical differences existed between group A (advanced Brain Food®) and group B (Quietude®) at assessment period 2 (The p-value was greater than 0.05). At assessment 1 (P-value= 0.019), assessment 2 (P-value 0.004) and assessment 4 (P-value= 0.011) a statistical difference was seen between group A and group B.

The category of Psychosomatic Problems on the SBL is primarily used to monitor side effects to stimulant medication (Strauss, 2000). The intra-group comparison for this test category shows that group A (Advanced Brain Food®) and group B (Quietude®) were not similar at the start of the research trial, and this might explain the significant statistical differences seen in group A. The differences between the two groups can be attributed to the fact that subjects taking stimulant medication have different responses

with regards to their behaviour (Karen et al. 1997). Although this test category is included in the SBL it is inappropriate in this research because the interventions used (Advanced Brain Food® and Quietude®) can not be considered stimulant medications.

CONCLUSION

Subjects taking Advanced Brain Food® during the trial performed better than the group taking Quietude® with regards to conduct and impulsivity according to the Student Behaviour Log (SBL), with a significant difference between groups only being noticeable after four weeks of treatment. The groups performed similarly regarding inattention, hyperactivity and anxiety (no significant differences were seen at the four different assessment periods).

Supplementation and treatment with Advanced Brain Food® cannot claim to replace effective psychological interventions but merely help to correct deficiencies. The fact that an improvement was noted in this treatment group signifies that further research is necessary to establish the exact role of such interventions in the treatment of ADD/ ADHD.

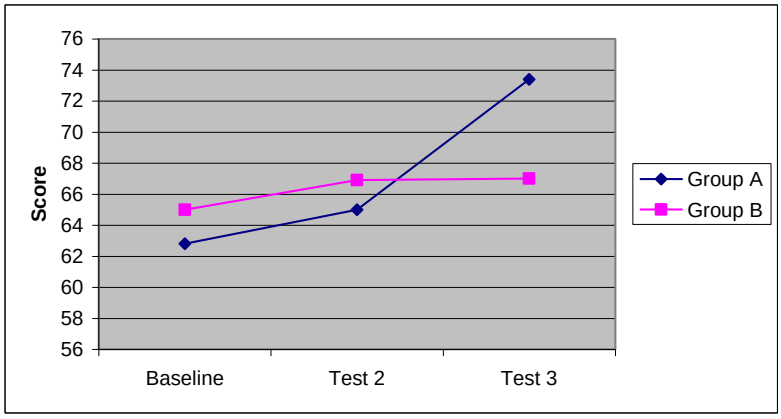
Children Checking Task

The Children's Checking Task (CCT) was used to evaluate sustained attention and vigilance before, during, and at the end of the treatment period. Impairments in concentration and attention may result in a shortened attention span, distractibility,

susceptibility to confusion, and unpredictable performance (Strauss, 2000). The CCT was used to evaluate the participant's attention span over a period.

FIGURE 4.14

LINE GRAPH OF MEAN SCORES OBTAINED FOR CCT 1- CCT4



A general improvement was seen in group A and B during the three assessments. The reason for a general improvement across both groups can be attributed to the so-called "practice effect" (Bazier, 2001). If each subject provides scores for each of the treatment

levels in an experiment then they may improve simply through the effect of practice on providing scores.

Although the “practice effect” can be held responsible for the improvement in overall performance seen in the two groups, group A (Advanced Brain Food®) still scored significantly higher for all tests.

INTRA-GROUP FINDINGS FOR GROUP A

The Friedman's test was used for this analysis. Where statistically significant results were found the Wilcoxon's test was done to establish where exactly the differences occurred.

For the category, CCT 1(letters) and CCT 3(symbols) the Friedman's test indicated a statistically significant difference (p=0.001 for both CCT1 and CCT3). This indicated that there was an increase in scores obtained for this category within the group. On further examination using the Wilcoxon's test it became apparent that a maximum improvement occurred at assessment 2 (at three weeks) and was significant up to assessment 3 (a~~A~~t six~~6~~ weeks).

For the category, CCT 2 (numbers) the Friedman's test indicated a statistically significant difference (p=0.007). This indicated that there was an increase in scores obtained for this

category within the group. Wilcoxon's test indicated that the statistically significant result was noticeable at week 6 (Assessment 3).

For the category, CCT 4 (words) there was no statistically significant difference noted between the three assessment periods. A possible reason for this is that CCT4 (words) was the last page (total pages was 5) of the Children's Checking Task (CCT). The time constraint of ten minutes made subjects anxious to finish the CCT which could have led to a decrease in concentration. A further possibility is that the age group (8-13 years) made this test difficult for younger participants. A recommendation for future research is that the time constraint of ten~~10~~ minutes be extended to 15 minutes or that only one age group is to be used in such a clinical trial to enable the participants to finish the CCT in due time.

INTRA-GROUP FINDINGS FOR GROUP B

The Friedman's test was used in this analysis. For the test categories (Letters, Numbers, Symbols and Words) the results indicated that there were statistical~~ly~~ differences found during the clinical trial. In all cases the p-value was greater than 0.05. This is indicative that the group taking Quietude® (Group B) did not show any progress or regression during the clinical trial.

INTER-GROUP COMPARISON FOR GROUP A AND B

The Mann Whitney U-test was used to examine significant differences between group A and group B subjects in their assessment scores at the three different assessment periods.

For test category 1 (CCT1-Letters) and 2 (CCT 2- Symbols)

No statistically significant results were noted for group A and B between score 1 (baseline) and score 2 (at three weeks). A statistical significant result was noted at score 3 (six~~6~~ weeks). For CCT1 the p-value was 0.015 at score 3. For CCT3 the p-value was 0.019 at score 3.

For test category 2 (CCT 2-Numbers) and 4 (CCT4-Words)

No statistically significant difference was noted for CCT 2 (numbers) nor was there a statistically significant difference in test scores obtained for all the measurements between group A and group B. The p-value for all three assessments was greater than 0.05.

CONCLUSION

The main aim of the Children's Checking Task was to evaluate the participant's attention span over a period of time. An improvement in the overall test result i.e. increased scores (percentage) would indicate an increased sustained attention level (Strauss, 2000).

From the results it is apparent that subjects taking Advanced Brain Food® during the clinical trial showed positive results in two areas (CCT1 and CCT3) of the Children's Checking Task after 3 weeks. After a period of six~~6~~ weeks a further improvement was seen in yet another component (CCT 2) of the CCT.

Subjects taking Advanced Brain Food® during the trial showed a definite improvement with regards to motor-visual skills and sustained attention according to the Children's

Checking Task (CCT), with significant differences noticeable after 3 weeks of treatment and sustainable up to six weeks where further improvement occurred.

Subjects taking Quietude® during the trial did not improve or regress significantly during the clinical trail. Although the group taking Advanced Brain Food® performed better than the group taking Quietude® with regards to sustained attention levels, more research needs to be conducted to establish if Quietude® might have a more positive result on other symptoms of ADHD (e.g. sleep, anxiety) and if Advanced Brain Food® could sustain this improvement over longer periods of time.

The relatively short period of assessment might be a reason for results obtained from the group taking Quietude®. Schools were not willing to risk disruption to normal school routine for longer periods of time (Middleborough, 2001). A longer assessment period of three to six months would have given a more accurate reflection of a child's progress in terms of this new proposed treatment.

Initially the research student wanted to include a placebo group to establish the true efficacy of Advanced Brain Food® and Quietude® in the management of ADHD signs and symptoms. Durban Iinstitute of Technology however rejected this proposal because they felt that this was an extremely vulnerable group and that each subject participating in the clinical trial should receive some sort of treatment (either Advanced Brain Food® or Quietude®) for the duration of the clinical trial. For future research purposes a placebo group should be included to evaluate what, if any, changes occur between the placebo group versus Advanced Brain Food® and the placebo group versus Quietude®.

CHAPTER 6

CONCLUSIONS AND RECOMMENDATIONS

6.1 CONCLUSIONS

The aim of this study was to determine and compare the relative efficacy of a nutritional supplement (Advanced Brain Food®) and a homoeopathic complex (Quietude®) in the management of ADHD. Using the ADHD-IV Rating Scale, participants were assessed on a fortnightly~~two weekly~~ basis for six weeks to determine what, if any, progress was made. Intra-group comparisons of each of the groups showed that there was no statistically significant improvement within the individual scores. Inter-group comparisons however revealed that there was a downward trend or improvement

concerning the mean scores of the Advanced Brain Food® and ~~,~~ to a lesser extent this was seen in the Quietude® group~~.~~, T~~t~~his indicates there was some slight improvement (not statistically significant) in the participants of these two groups.

The Student Behaviour Log (SBL) examined the following aspects of the subjects: Verbal-linguistic, Logical-mathematical, Visual spatial, Body-kinaesthetic, Musical-rhythmical, Interpersonal and Naturalist behaviours. It is a useful assessment technique for parents/teachers that have an ADHD child. The SBL results have been divided up into their respective categories and will be discussed in terms of intra-group and inter-group comparisons. For the intra-group comparison results revealed that there was no statistically significant difference for the test categories: conduct problems, inattention, psychosomatic problems, impulsivity and hyperactivity.

There was a significant result noted for psychosomatic problems, which is generally used as a measure for the effects of stimulant medications

The inter-group comparisons showed a statistically significant difference in a number of areas. The first difference that was noted was between groups A~~one~~ and ~~two~~B for the category of Conduct problems. This difference may be explained by the fact that the mean scores at the initial presentation of symptoms was significantly lower in the Advanced Brain Food® as compared to the Quietude® group. For the category Impulsivity this difference was marked again on the third questionnaire where the Advanced Brain Food® group differed from the Quietude® group, although both of the groups signified a progressive improvement. The same significant difference was noted for the Psychosomatic problems and Impulsivity at assessment 3.

The Children's Checking Task (CCT) was the only test to be completed by the participants. It was used to evaluate sustained attention levels. A general improvement was seen in group A and group B subjects. Although it can be argued that children in the study became familiar with the test protocol (the reason for the total increase in scores obtained), group A subjects still performed better during these tests. In the inter-group comparison of the total scores (CCT1, CCT2, CCT3) a significant improvement was shown in the Advanced Brain Food® group as compared to the Quietude® group. As a result it can be stated that Advanced Brain Food® was a more effective intervention than Quietude® as it managed to significantly improve the attention span of the subjects during the clinical trail. Although the homoeopathic complex (Quietude®) did not show any statistically significant improvement, it was clear that there was a slight improvement in sustained attention levels thus further research should be done to establish if a longer treatment period might show more significant improvements.

The fact that an improvement was noted in the treatment groups signifies that further research is necessary to establish the exact role such interventions may play in the treatment of ADD/ADHD. Recommendations could then be made with regard to the time period over which supplementation should occur.

Although a consistent diagnostic test for ADHD does not exist, evidence supporting the validity of the disorder can be found. Further research will need to be conducted with respect to the dimensional aspects of ADHD, as well as the comorbid (coexisting) conditions present in both childhood and adult ADHD. Therefore, an important research need is the investigation of standardi~~s~~zed age-and gender-specific diagnostic criteria.

The impact of ADHD on individuals, families, schools, and society is profound and necessitates immediate attention because a considerable share of resources from the health care system and various social service agencies is currently devoted to ADHD, often in a non-integrated manner. Resource allocation based on better cost data leading to integrated care models needs to be developed for individuals with ADHD.

Effective treatments for ADHD have been evaluated primarily for the short term (approximately 3 months). These studies have included randomi~~z~~s~~z~~ed clinical trials that have established the efficacy of stimulants and behavioural treatments for positive effects on the defining symptoms of ADHD and associated aggressiveness. Lack of consistent improvement beyond the core symptoms leads to the need for treatment strategies that utili~~z~~s~~z~~e combined approaches. At the present time, there is a paucity of data providing information on long-term treatment beyond 14 months. Although trials combining drugs and behavioural modalities are underway, conclusive recommendations, concerning treatment for the long term cannot be made easily.

The risks of treatment, particularly the use of stimulant medication, are of considerable interest. Substantial evidence exists of wide variations in the use of psychostimulants across communities and physicians, suggesting no consensus among practitioners regarding which ADHD patients should be treated with psychostimulants. As measured by attention/activity indices, patients with varying levels and types of problems (and even possibly unaffected individuals) may benefit from stimulant therapy. However, there is no evidence regarding the appropriate ADHD diagnostic threshold above which the benefits of psychostimulant therapy outweigh the risks.

Existing diagnostic and treatment practices, in combination with the potential risks associated with medication, point to the need for improved awareness by the health service sector concerning an appropriate assessment, treatment, and follow-up. A more consistent set of diagnostic procedures and practice guidelines is of utmost importance.

Current barriers to evaluation and intervention exist across the health and education sectors. The cost barriers and lack of coverage preventing the appropriate diagnosis and treatment of ADHD and the lack of integration with special educational services represent considerable long-term cost for society. The lack of information and education about accessibility and affordability of services must be remedied.

Finally, after years of clinical research and experience with ADHD, our knowledge about the cause or causes of ADHD remains speculative. Consequently, we have no strategies for the prevention of ADHD.

6.2 RECOMMENDATIONS

There are a number of recommendations that can be made with regard to future studies on this or related topics:

If further studies are conducted in this field, the author recommends that Teacher-rating Scales be incorporated into the study, in conjunction with Parental-rating Scales. Teacher-rating Scales have been found to be more reliable and sensitive than Parent-ratings in some studies (Barkley, 1981).

The research should be conducted over a longer period like three to six months as some of the patients in the treatment groups reported ongoing progress after the ~~6~~six weeks of treatment.

Additional funding should be made available for a proper psychiatric evaluation of the children. Some potential participants were rejected for the trial because they did not have proper diagnostic criteria available at the time of the initial interview.

The sample groups should be much larger to show a higher statistical significance between the treatment groups.

Although this research was aimed at a vulnerable group, placebo groups should be included in the study. Parents of concerned parties will have to give consent for such research to be conducted. (Double-blind placebo-controlled cross-over studies should be desi~~n~~gned to truly test the effect of alternative medications.

Although an independent diagnostic test for ADHD does not exist, there is evidence supporting the validity of the disorder. Further research is needed on the dimensional aspects of ADHD, as well as the co~~-~~morbid conditions present in both adult and childhood forms.

~~-~~Basic research is needed to better define ADHD. This research includes the following: (1) studies of cognitive development and cognitive processing in ADHD and (2) brain

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imaging studies before the initiation of medication and following the individual through young adulthood and middle age.

Additional studies are needed for the inattentive type of ADHD, especially since it might include a higher proportion of girls than the subtypes with hyperactivity/impulsitivity.

More studies are needed to determine the risk and benefits associated with treating children younger than the age of 5 five years with stimulants.

Using the same principle of this research the treatment could be applied to different conditions like those suffering with chronic insomnia, Alzeimer'sAlzheimer's disease, bipolar disorders to establish what success these conditions would show to the same treatment. There are an abundance of people who suffer from these conditions and as such it would be easier to get volunteers particularly for longer studies.

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APPENDIX A

FOR ATTENTION: Dr. L. STRAUSS

John-John Lottering
57 Tunny Street
Groeneweide
Elspark
1423
August 2003

Dr. Strauss
P.O. Box 28377
Kensington
2101

As per requirement of Durban Institute of Technology for the completion of my degree (M. Tech: Hom) I need to conduct a research project. The title of the research project is as following:

The relative efficacy of Advanced Brain Food® and a Homeopathic Complex (Quietude®) in the management of ADHD in males between the ages of 8 and 13 years.

I would like to make a request for permission to use the facilities at your clinic. The request is being made in anticipation of my research idea being approved, at this stage it has only been approved with corrections.

I would need to make use of the dispensing facilities to distribute the remedies as well as to store the remedies, which will be required for the research project. I would also like to request permission to make use of a clinic consulting room for the purpose of interviewing participants in the research project.

If this request is approved I will also require a qualified practitioner to be available to sign scripts for dispensing of treatment to the patients. I am quite happy to negotiate any times you may find acceptable. Please feel free to contact me with regards to the above:

Tel: 084 555 9977
Tel: 011 616 8933 (w)
E-mail: jlottering@hotmail.com

Yours Sincerely,

John-John Lottering
(Homeopathy Master's Student)

APPENDIX B

INFORMED CONSENT FORM (PARENT/GUARDIAN)

TITLE OF RESEARCH PROJECT:

The relative efficacy of a Nutritional Supplement and a Homeopathic Complex in the management of ADHD (Attention Deficit Hyperactivity Disorder) in males between the ages of 8 and 13 years.

NAME OF SUPERVISOR: Dr. Leon Strauss

NAME OF CO-SUPERVISOR: Dr David Naude

DATE OF FIRST APPOINTMENT: _____

Patient's Full Name: _____

PLEASE CIRCLE THE APPROPRIATE ANSWER

1. Have you read the research information sheet? YES / NO
2. Have you had an opportunity to ask any questions regarding this study? YES / NO
3. Have you received satisfactory answers regarding this study? YES / NO
4. Have you had an opportunity to discuss the study? YES / NO
5. Have you received enough information about the study? YES / NO
6. Who have you spoken to? _____
7. Do you understand the implications of your involvement in this study? YES / NO
8. Do you understand that you are free to withdraw from this study?
   a) at any time, and YES / NO
   b) Without having to give reason for withdrawing? YES / NO
9. Do you agree to voluntary participate in this study? YES / NO
10. Do you understand the difference between an allopathic and Homoeopathic treatment? YES / NO

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

I _____ hereby give consent for the proposed procedure to be performed on the abovementioned patient as part of the research project as detailed above.

PARENT/GUARDIAN * Name: _____ **Signature** _____
(in block letters)

WITNESS: Name: _____ Signature _____
(in block letters)

RESEARCH STUDENT:
JOHN-JOHN LOTTERING Signature: _____

APPENDIX C

INFORMED ASSENT FORM

RESEARCH TITLE

THE EFFECTIVENESS OF A NUTRITIONAL SUPPLIMENT AND A HOMOEOPATHIC PREPARATION IN THE MANAGEMENT OF ATTENTION DEFICIT DISORDER IN BOYS

Name of Supervisor: Dr. Leon Strauss

Name of Co-Supervisor: Dr David Naude

Patient Full Name: _____

DATE: _____

Please circle the answer once you have read the questions

1.	Have you read the information letter?	YES / NO
2.	Did you have chance to ask questions?	YES / NO
3.	Did you get satisfactory answers to the questions?	YES / NO
4.	Do you understand why the study is being done?	YES / NO
5.	Do you understand what is expected from you?	YES / NO
6.	Do you agree to willingly partake in the study?	YES / NO
7.	Do you understand that you are free to withdraw from the Study at any time without giving a reason?	YES / NO

If you have answered NO to any of the abovementioned questions, please ask some more questions before you sign.

I, _____, hereby give consent to participate in the research study.

Patient/ Subject Signature: _____

Witness:
NAME: _____ Signature: _____

Research Student.

JOHN-JOHN LOTTERING Signature: _____

Research Supervisor

Dr. LEON STRAUSS Signature _____

Appendix C2
Subject Information Letter (Child)

Title of research project:

The effectiveness of a Nutritional Supplement and a Homoeopathic Complex in the management of Attention Deficit Hyperactivity Disorder (ADHD) in boys between the ages of 8 and 13 years.

Introduction:
Attention Deficit Hyperactivity Disorder (ADHD) is a problem affecting the brain and your ability to concentrate. This condition is treatable but not curable.
Ritalin is often used by doctors to try and correct this problem but in some cases it does not work, or it has to many bad effects on the body.
On the other hand nutritional treatment has proven very helpful in managing this condition without the bad effects on the body.
The research is being done to see if Attention Deficit Hyperactivity Disorder can be managed without taking Ritalin®

Advanced Brain Food:
This is a nutritional supplement in tablet form. It was designed to feed the brain and correct nutritional deficiencies that a child with ADHD might present with.

Quietude:
This is a natural medication in a syrup form with the main objective to calm and focus a person. It is natural and will have no bad effects on the body.

Risks involved in partaking in the study:
It is important to state that you as participant in the study is free to withdraw from the study at any time and without giving a reason.
If you were taking Ritalin® you must stop taking it for 6 weeks. We are testing to see if we can use something else in the place of Ritalin®.

Risks:
If you were on Ritalin or any other medication, you might find it difficult to focus and concentrate. Your old symptoms might re-appear.
The study must be done during a school term, because then you are not on holiday and you must do what you are told to. You might find it difficult to do everything your teacher asks you to do.

Requirements for participating in the trial:

1. You must be a boy.
2. You must be between the ages of 8 and 13 years.
3. You must not take Ritalin or any other medicine for the management of ADHD.
4. You must be in possession of a doctor's letter stating that you have ADHD.
5. You must have a signed consent form from your parent/guardian.

Confidentiality:

1. The research student will not know what treatment you are given.
2. Your name will not appear in the final write-up of the trial.
3. All information given during the trial will only be seen by the research student and his supervisor. These documents will be destroyed after four years.

How you will be tested:

1. You will be asked to complete four tests at four different times
2. Your parent/guardian must complete three forms on four different occasions on your behalf.

Where will you be tested?

All interviews and tests will be done at Dr. Leon Strauss's rooms in Edenvale.
This trial will be done over six weeks and you will be required to meet the research student at the Doctor's rooms for the duration of the trial at least five times.

Should you require any further information please do not hesitate to contact my supervisor or me at any time.

Kind regards

John-John Lottering
(Homeopathic Master's Student)
Cell: 084 555 9977

Dr. Leon Strauss
(Supervisor)
Cell: 0823303966

APPENDIX D

INFORMED CONSENT FORM

TITLE OF RESEARCH PROJECT:

The relative efficacy of a Nutritional Supplement and a Homeopathic Complex in the management of ADHD (Attention Deficit Hyperactivity Disorder) in males between the ages of 8 and 13 years.

NAME OF SUPERVISOR: Dr. Leon Strauss

NAME OF CO-SUPERVISOR: Dr David Naude

DATE OF FIRST APPOINTMENT: _____

Patient's Full Name: _____

PLEASE CIRCLE THE APPROPRIATE ANSWER

1. Have you read the research information sheet? YES / NO
2. Have you had an opportunity to ask any questions regarding this study? YES / NO
3. Have you received satisfactory answers regarding this study? YES / NO
4. Have you had an opportunity to discuss the study? YES / NO
5. Have you received enough information about the study? YES / NO
6. Who have you spoken to? _____
7. Do you understand the implications of your involvement in this study? YES / NO
8. Do you understand that you are free to withdraw from this study?
   a) at any time, and YES / NO
   b) Without having to give reason for withdrawing? YES / NO
9. Do you agree to voluntary participate in this study? YES / NO
10. Do you understand the difference between an allopathic and Homoeopathic treatment? YES / NO

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

I _____ hereby give consent for the proposed procedure to be performed on the abovementioned patient as part of the research project as detailed above.

PARENT/GUARDIAN * Name: _____ **Signature** _____
(in block letters)

WITNESS: Name: _____ Signature _____
(in block letters)

RESEARCH STUDENT:
JOHN-JOHN LOTTERING Signature: _____

APPENDIX K 1

Instructions: Cross out all the letters that are the same as the one in the block.

E.G.

T												
G	S	W	T	U	J	X	T	T	E	O	T	H
A	W	T	U	M	T	V	N	Q	Y	T	D	Y
D	E	W	T	H	K	T	W	D	H	K	T	N

Instructions: Cross out all the numbers that are the same as the one in the block.

E.G.

7												
2	4	1	7	9	5	3	6	7	2	7	8	6
6	5	9	3	6	7	9	6	3	6	1	0	4
9	1	6	0	6	3	5	9	6	8	8	5	3

Instructions: Cross out all the symbols that are the same as the one in the block.

E.G.

%												
$	&	*	%	>	{	@	!	<	?	\	%	#
%	!	<	?	&	}	#	?	!	%	?	*	%
@	[	?	\	#	@	$	%	!	}	[	%	$

Instructions: Cross out all the symbols that are the same as the two in the block.

E.G.

% and ?												
$	&	*	%	?	}	@	!	<	?	|	%	#
%	!	<	?	&	{	#	?	!	%	@	^	%
@	[	?	\	#	@	$	%	*	}	}	%	$

Instructions: Cross out all the words that are the same as the one in the block.

CAT		
SAT	TAR	HUM
BUG	CAT	DEN
CAT	WIN	CUT
RUN	LIP	BOY
MAT	MAP	CAT
LOG	RUG	FAR
CAT	HIT	CAT
NUN	CAT	LID

APPENDIX F
Subject Information Letter

Title of Research Project:

The relative efficacy of a Nutritional Supplement and a Homeopathic Complex in the management of Attention Deficit Hyperactivity Disorder (ADHD) in males between the ages of 8 and 13 years.

Introduction:

Attention Deficit Disorder (ADD) and is a syndrome, which is characterized by serious and persistent difficulties resulting in poor attention span, weak impulse control and hyperactivity but not in all cases. A variant of this condition is associated with hyperactivity (ADHD). According to orthodox medicine it is a treatable (not curable) complex disorder, which affects approximately 3-6% of the general population (NIH Consensus Statement 1998).

Many hyperactive children are not evaluated for chemical or allergic factors, nor are they treated nutritionally. These factors often get ignored and more often than not they are given orthodox medication for the presenting ailment i.e. Ritalin®

Diagnosis of ADD/ADHD have risen more than fifteen-fold in the last decade, and prescriptions of Ritalin® and other stimulant drugs are not far behind. A recent study done has shown that Ritalin® can worsen the behaviour of more children than it helps (Holford, 2002).

The current study is being conducted to evaluate the potential alternatives for the management of ADHD.

Nutritional Supplementation

This nutritional supplement is a registered supplement and is approved by the Medicines Control Council of South-Africa. The manufacturer is a very well known and reputable company and has a ISO9000 rating.

This product is a natural nutritional supplement formulated for the treatment of poor attention span and memory. It has proven very effective in the treatment of nutritional related memory loss. The main objective of this formulation is aimed at correcting nutritional/chemical imbalances that a child with ADHD might present with.

Homoeopathic Treatment

This product is a registered French Homoeopathic Remedy and is made in accordance with strict French Homeopathic Pharmacopoeia standards. It is a safe mode of treatment with no side effects.
Homoeopathic intervention offers a possibility of effectively treating/managing people presenting with ADHD.

Expected Benefits

- Should this treatment prove beneficial for the management of ADHD, parents/guardians will not have to administer Ritalin® or similar type drugs to their children. The risk of possible side effects of being on Ritalin® will be eliminated.

- Parents/guardians can manage the condition without the introduction of chemicals.
- It would be financially beneficial to the parent/guardian because the cost of either the nutritional supplement or the homoeopathic complex is a lot less

Risks involved in the study:

It is important to state that a child is free to withdraw from the study at any time without reason.

Risks:

- Should the proposed treatment prove to be ineffective, the possibility exists that previous ADHD symptoms might re-appear.
- Conducting the trial during a school term might result in the child neglecting his education and behavior at school. (Unfortunately the trial cannot be conducted during a school holiday because the child is not involved in cognitive exercises, but would rather relax in front of the television or at home with much less stress placed upon him)
- The trial will be conducted very early during a school term, so that possible disruptions in school activities can be minimized.

Selection Criteria:

As the child arrives for the initial interview they will be assessed according to the following selection criteria:

a) ***Inclusion Criteria:***

- They must be males between the ages of 8-13.
- They must be in possession of a doctor's certificate, which diagnoses them as having ADHD and must be in possession of a completed Conner's Rating Scale issued by a psychologist.
- They must be candidates for Ritalin® usage (as prescribed by a doctor and/or psychologist), or they must have been taking Ritalin® for at least three months prior to the study.
- They must for a period of one week before the research and for the duration of the trial (6 weeks) abstain from taking any of their prescribed allopathic medication for the treatment of ADHD. (This is to anticipate any withdrawal symptoms that might occur as a result of taking the child of Ritalin®).

b) ***Exclusion Criteria:***

- Children who suffer from epilepsy.
- Children who cannot abstain from their relevant chronic medication (e.g. Ritalin®).

Once accepted into the study, the parents/guardians of the children will be required to complete an informed consent form. The child will be required to complete an assent form.

Treatment Groups:

The children will randomly be divided into two equally sized groups.

a) Group 1:

This group will receive the nutritional supplement***.***

b) Group 2:
They will receive the homoeopathic complex

Confidentiality:

a) Neither the research student nor the research supervisor will know to which treatment group a child belongs.
b) All names of children participating in the research will be discarded in the final write-up.
c) All questionnaires will be kept in patient folders for the duration of the study and for 4 years there after and will be accessible to only the researcher and his supervisor/supervisors. After a period of five years all questionnaires will be destroyed by means of shredding.

Assessment Techniques:
The assessments will consist of diligent tasks and behavior logs that will be completed by the parents/guardians on 4 different occasions.
The children will be required to complete a simple test on 4 different occasions.
On completion of the trial all these questionnaires will be handed back to the research student for the required statistical analysis.

Location of the study:
The study will be conducted at Dr. L. Strauss's consulting rooms, situated at the corner of 1st and Linksfield road, Edenvale. This venue will be used for a period of six weeks (the duration of the trial period. The exact days and dates of consultations will still be decided.

In Participating in this study you will contribute to medical knowledge, which might result in a greater efficacy in the management of ADHD.

Should you require any further information please do not hesitate to contact my supervisor or me at any time.

Yours Sincerely,

John-John Lottering
(Homoeopathy Master's Student)
Cell: 084 555 9977

Dr. Leon Strauss
(Supervisor)
Cell: 082 330 3966

APPENDIX G

ADHD RATING SCALE-IV: HOME VERSION

Child's name _____. Age _____. Grade _____.Completed by: Mother . Father . Guardian . Grandparent .

Circle the number that *best describes* your child's behaviour over the past week.

	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 organising 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 or 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

APPENDIX H
ADHD RATING SCALE –IV: HOME VERSION
SCORING SHEET FOR BOYS

Child's name _____. Date _____. Age _____.

%ile	HI 5-7	HI 8-10	HI 11-13	HI 14-18	IA 5-7	IA 8-10	IA 11-13	IA 14-18	Total 5-7	Total 8-10	Total 11-13	Total 14-18	%ile
99+	**26**	**25**	**25**	**19**	**24**	**26**	**27**	**25**	**43**	**49**	**51**	**41**	**99+**
99	**25**	**24**	**24**	**18**	**23**	**25**	**26**	**24**	**42**	**48**	**50**	**40**	**99**
98	**22**	**21**	**21**	**16**	**20**	**22**	**24**	**23**	**40**	**42**	**47**	**36**	**98**
97	**21**	**18**	**18**	**16**	**20**	**19**	**22**	**16**	**37**	**37**	**38**	**32**	**97**
96	**19**	**17**	**18**	**15**	**18**	**18**	**21**	**18**	**36**	**34**	**37**	**30**	**96**
95	**17**	**17**	**18**	**13**	**16**	**17**	**20**	**17**	**34**	**31**	**35**	**28**	**95**
94	**17**	**15**	**18**	**12**	**15**	**16**	**19**	**16**	**33**	**29**	**34**	**27**	**94**
93	**17**	**15**	**16**	**11**	**15**	**15**	**18**	**15**	**30**	**27**	**34**	**27**	**93**
92	**16**	**14**	**16**	**11**	**14**	**15**	**18**	**14**	**30**	**26**	**33**	**26**	**92**
91	**16**	**14**	**15**	**11**	**13**	**14**	**18**	**14**	**29**	**26**	**32**	**25**	**91**
90	**15**	**13**	**14**	**10**	**13**	**14**	**18**	**14**	**29**	**25**	**31**	**23**	**90**
89	**14**	**13**	**13**	**10**	**12**	**14**	**17**	**13**	**28**	**24**	**30**	**21**	**89**
88	**14**	**12**	**12**	**10**	**12**	**13**	**17**	**12**	**27**	**24**	**30**	**21**	**88**
87	**13**	**11**	**11**	**9**	**12**	**13**	**16**	**12**	**25**	**23**	**28**	**20**	**87**
86	**13**	**11**	**10**	**9**	**12**	**12**	**16**	**11**	**22**	**23**	**26**	**20**	**86**
85	**12**	**10**	**10**	**8**	**11**	**12**	**14**	**11**	**22**	**22**	**23**	**19**	**85**
84	**12**	**10**	**9**	**8**	**11**	**12**	**14**	**10**	**21**	**21**	**22**	**18**	**84**
80	**11**	**9**	**8**	**7**	**9**	**11**	**10**	**9**	**19**	**20**	**19**	**16**	**80**
75	**9**	**8**	**7**	**6**	**8**	**9**	**9**	**8**	**18**	**17**	**14**	**13**	**75**
50	**5**	**4**	**3**	**2**	**5**	**6**	**5**	**4**	**10**	**10**	**7**	**7**	**50**
25	**3**	**2**	**1**	**0**	**2**	**3**	**2**	**1**	**6**	**5**	**4**	**3**	**25**
10	**1**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**2**	**1**	**1**	**0**	**10**

APPENDIX I

Diagnostic Criteria

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 level:
    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 schoolwork, chores, or duties in the workplace (not due to oppositional behavior 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 schoolwork 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 squirms in seat
    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 adolescents or adults, may be limited to subjective feelings of restlessness)
d. often has difficulty playing or 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

g. often blurts out answers before questions have been completed
h. often has difficulty awaiting turn
i. often interrupts or intrudes on others (e.g., butts into conversations or games)

B. Some hyperactive-impulsive or inattentive 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 Disorder and are not better accounted for by another mental disorder (e.g., Mood Disorder, Anxiety Disorder, Dissociative Disorder, or a Personality Disorder).

Specify Type:

- **Attention-Deficit/Hyperactivity Disorder, Combined Type:** if both Criteria A1 and A2 are met for the past 6 months
- **Attention-Deficit/Hyperactivity Disorder, Predominantly Inattentive Type:** if Criterion A1 is met but Criterion A2 is not met for the past 6 months
- **Attention-Deficit/Hyperactivity Disorder, Predominantly Hyperactive-Impulsive Type:** if Criterion A2 is met but Criterion A1 is not met for the past 6 months

Note: For individuals (especially adolescents and adults) who currently have symptoms that no longer meet full criteria, "In Partial Remission" should be specified.

Differential Diagnosis

Age-appropriate behaviors in active children; Mental Retardation; understimulating environments; oppositional behavior; another mental disorder; Pervasive Developmental Disorder; Psychotic Disorder; Other Substance-Related Disorder Not Otherwise Specified.

APPENDIX J
STUDENT BEHAVIOUR LOG (Lazear, 1999)

STUDENT NAME:
_____

AGE: _____ **DATE OF OBSERVATION:**_____

Indicate the degree to which you observe the stated behaviour or characteristic in each student using the following scale:
0 = Uncertain; 1=Does not fit at all; 2= fits slightly; 3= fits moderately; 4= fits strongly

VERBAL-LIGUISTIC BEHAVIORS					
Loves talking, writing, and reading almost anything	**0**	**1**	**2**	**3**	**4**
Precisely expresses her- or himself both in writing and talking	**0**	**1**	**2**	**3**	**4**
Enjoys public speaking.	**0**	**1**	**2**	**3**	**4**
Is sensitive to impact of words and language of others.	**0**	**1**	**2**	**3**	**4**
LOGICAL-MATHEMATICAL BEHAVIOR					
Is good at finding and understanding patterns	**0**	**1**	**2**	**3**	**4**
Is quick at solving a variety of problems	**0**	**1**	**2**	**3**	**4**
Can remember thinking formulas and strategies	**0**	**1**	**2**	**3**	**4**
Likes to identify, create and sort things into categories	**0**	**1**	**2**	**3**	**4**
VISUAL-SPATIAL BEHAVIOURS					
IS helped by visuals and manipulatives	**0**	**1**	**2**	**3**	**4**
Likes painting, drawing and working with clay	**0**	**1**	**2**	**3**	**4**
Has a good sense of direction and understanding of maps	**0**	**1**	**2**	**3**	**4**
BODILY-KINESTETIC BEHAVIORS					
Has difficulty sitting still or staying in seat	**0**	**1**	**2**	**3**	**4**
Uses body gestures and physical movement to express him or herself	**0**	**1**	**2**	**3**	**4**
IS good in sports; is well-coordinated physically	**0**	**1**	**2**	**3**	**4**
Likes to invent things, put things together and take them apart	**0**	**1**	**2**	**3**	**4**
MUSICAL-RYTHMIC BEHAVIORS					
Hums quietly to him or herself while working or walking	**0**	**1**	**2**	**3**	**4**
Can remember songs or rhymes easily	**0**	**1**	**2**	**3**	**4**
Senses musical elements in unusual or nonmusical situations	**0**	**1**	**2**	**3**	**4**
INTERPERSONAL BEHAVIORS					
Has an irresistible urge to discuss almost everything with others	**0**	**1**	**2**	**3**	**4**
Is good at listening and communicating	**0**	**1**	**2**	**3**	**4**
Senses the moods and feelings of others	**0**	**1**	**2**	**3**	**4**
Is a good, effective team player	**0**	**1**	**2**	**3**	**4**
INTRAPERSONAL BEHAVIORS					
Is individualistic and independent; Is not concerned about others' opinions	**0**	**1**	**2**	**3**	**4**
Is quiet, very self-reflective and aware	**0**	**1**	**2**	**3**	**4**
Asks questions relentlessly; Has avid curiosity	**0**	**1**	**2**	**3**	**4**
Is able to express inner feelings in a variety of ways	**0**	**1**	**2**	**3**	**4**
NATURALIST BEHAVIORS					
Is drawn to the external, natural environment	**0**	**1**	**2**	**3**	**4**
Has a strong curiosity about and attraction to animals and insects	**0**	**1**	**2**	**3**	**4**
Recognises and is fascinated by patterns in nature	**0**	**1**	**2**	**3**	**4**

APPENDIX K 1

Instructions: Cross out all the letters that are the same as the one in the block.

E.G.

T												
G	S	W	T	U	J	X	T	T	E	O	T	H
A	W	T	U	M	T	V	N	Q	Y	T	D	Y
D	E	W	T	H	K	T	W	D	H	K	T	N

Instructions: Cross out all the numbers that are the same as the one in the block.

E.G.

7												
2	4	1	7	9	5	3	6	7	2	7	8	6
6	5	9	3	6	7	9	6	3	6	1	0	4
9	1	6	0	6	3	5	9	6	8	8	5	3

Instructions: Cross out all the symbols that are the same as the one in the block.

E.G.

%												
$	&	*	%	>	{	@	!	<	?	\	%	#
%	!	<	?	&	}	#	?	!	%	?	*	%
@	[	?	\	#	@	$	%	!	}	[	%	$

Instructions: Cross out all the symbols that are the same as the two in the block.

E.G.

% and ?												
$	&	*	%	?	}	@	!	<	?	|	%	#
%	!	<	?	&	{	#	?	!	%	@	^	%
@	[	?	\	#	@	$	%	*	}	}	%	$

Instructions: Cross out all the words that are the same as the one in the block.

CAT		
SAT	TAR	HUM
BUG	CAT	DEN
CAT	WIN	CUT
RUN	LIP	BOY
MAT	MAP	CAT
LOG	RUG	FAR
CAT	HIT	CAT
NUN	CAT	LID

APPENDIX K2

M

A F U M V W K L J F H M V A M J B H K M W S X M Q R T M O G H K T R W R L B M T H V Q M D H F M L N M J

M V M T J D M B H D C K F K M L A Q M I L M H L C H U D G N M V R X E M A L J T H Y O M A W D F C R U M

H M B S M C N O M Q F D V N R H M O K V E M A Q B M Y G R D M W V M H L Q F U M W A Q X L M U Y R J Q A

Y and O

O H O P Y S O Y K L G J N F T E O Y S G K U T R Y Q Z O J P J Y O S W I L Q Y A Q O G K L Q Y U O P D O

A Y T E O K G Y Q E F O Y H N K O Y R A X V F Y O W G N J O K Y Q W X Y O G J Y Q O P G O R D Q G W N J

A Y H F W Y K N J O Q G U L O Y N L Q O Y H D A Y O K D G D G O Q P W U E K E O P Y G O N F O W P H Y O

APPENDIX K 3

8

8 5 6 4 5 8 3 9 2 7 4 8 0 2 5 8 8 3 1 8 5 9 6 8 5 7 3 2 8 1 0 9 7 4 8 6 4 7 2 1 4 7 5 6 0 4 8 7 5 3 2 4

4 7 8 4 2 6 7 8 5 3 3 0 8 7 8 5 7 5 6 9 4 3 0 3 5 7 5 4 9 6 8 7 3 8 1 9 4 6 0 8 5 3 4 7 6 8 3 2 5 8 5 8

1 3 8 6 5 7 3 2 9 7 0 8 8 7 4 2 4 6 2 8 0 3 1 6 8 5 7 1 8 2 8 2 6 5 8 5 0 1 4 1 9 4 8 6 6 0 8 1 3 5 2 6

4 and 6

1 5 4 3 2 6 0 7 5 4 6 7 3 5 6 2 4 8 1 2 5 4 7 3 0 6 7 2 6 2 3 4 1 5 2 4 3 1 4 4 3 2 6 1 7 2 6 3 1 7 6 9

2 6 7 4 0 2 6 1 6 3 5 0 5 4 6 1 3 7 0 4 2 3 7 6 7 4 2 3 1 0 5 2 4 2 1 6 2 4 8 2 3 6 9 4 1 5 2 6 5 2 1 4

5 4 3 6 8 2 4 3 2 0 6 3 1 2 7 5 3 5 4 3 2 6 0 1 9 6 4 3 5 2 1 7 0 6 4 5 7 5 0 4 1 6 5 7 6 1 4 2 4 6 1 7

APPENDIX K 4

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! ? * } > \ # ! ^ $ > \ # @ > # ! $ & @ # ! & > # (! $ { * ! ? < ! >) % ? @ ! > &) $ * @ > ? % } > #

@ ! \ > * $ * @ > * ! ? @ # ! & * ? > & ! @ \ ? % > (! ? } { > % ! # (! > * } { \ # $ @ > ! & ? > # %

% $ > (! ? * } > \ # $ ^ $ > \ ! # @ # ! $ & @ ! & > $ # (! $! @ ! ? > > &) $ \ > @ # ! & ? $ # > <

APPENDIX K 5

		MAT		
MAT	GUT	FUN	JUG	POT
FAT	MAT	LIT	MAT	PEN
LIT	MAT	SIT	LIP	RAG
MAT	FAD	MAT	ASK	FAD
SIT	LIP	RAT	MOP	GUN
RAT	WIN	MAT	FUN	CUT
GUT	DOG	PEN	FAD	FAD
MAT	MAT	RAG	FUN	BUS
HUM	TOY	SAW	CAT	MUD
MOP	MAT	MOP	GUT	FAT
LIP	ASK	MAT	MAT	MAT
MAT	GUM	GUN	LIT	TAR
GUN	POT	JAR	FAD	DOG
FUN	BUS	MAT	SIT	CAT
PEN	DOT	HUM	GUN	ROT
NUT	MAT	TAR	POT	SAD
TOY	NUT	MUD	JAR	RIG
POT	WET	MAT	MAT	PUB
RAG	CUT	POT	DOG	MAT
MAT	SAD	LOG	HUM	NOD
TAN	JOY	HIT	RAT	VAT
LOG	SAT	CUT	WIN	FUR
KEG	HUB	NUN	MAT	KEG
RUN	HUG	DEN	SIT	NUN
RIM	GET	LOG	HAT	LOG
FOR	MAT	DOT	BUS	BOY
VET	DOT	NOD	SAW	BUS
MAT	MUD	JUG	KEG	MAT
NUN	SIT	MAT	JOY	WET
DEN	GAS	LID	HIT	PIG
SAT	PUN	MAT	PUN	LOG
CAR	DOT	MAP	MAT	MAP
BOY	MAT	SAD	DEN	VAT
MAT	HOT	WET	FUR	MAT
HUM	BUN	MAT	MAT	DOG
MAT	VET	HOT	NUN	LIP
TAR	HUM	NUN	TAR	MAP
GAT	DEN	MAT	LID	MAT
SUN	TAR	BOY	HOT	BUN
LID	RIM	RUN	RIM	CUT
MAT	SAT	CAR	NOD	PIG
MAP	PUB	MAT	HOT	MAT
MUG	MAT	HUG	HOT	RIG
BUS	TIP	RUG	GAS	JOY
ROT	MAT	CAR	RUN	GET

APPENDIX L4

CCT 4 - Words

COMBINED SCORES FOR CCT 4 (GROUP A & B)

PATIENT	CCT 4(40) Baseline	CCT 4(40) Test 2	CCT 4 (40) Test 3	Overall Performance (120)	Average Percentage
TR1	33	28	33	94	78.33%
TR3	36	35	40	111	92.50%
TR4	37	35	32	104	86.67%
TR5	30	33	29	92	76.67%
TR6	35	33	38	106	88.33%
TR7	31	29	29	89	74.17%
TR8	35	36	34	105	87.50%
TR9	36	38	29	103	85.83%
TR10	14	36	39	89	74.17%
TR11	31	34	33	98	81.67%
TR12	24	31	27	82	68.33%
TR13	36	30	33	99	82.50%
TR14	27	30	23	80	66.67%
TR15	29	33	37	99	82.50%
TR16	31	37	39	107	89.17%
TR17	34	33	35	102	85.00%
TR18	31	30	32	93	77.50%
TR19	28	34	32	94	78.33%
TR20	34	36	33	103	85.83%
TR21	17	24	32	73	60.83%
TOTAL	**609**	**655**	**659**		**80.13%**
Average S	**31.157895**	**33.21053**	**33**	**97.36842105**	**81.14%**

APPENDIX M
STUDENT BEHAVIOUR LOG RESULTS (SBL)

6. HYPERACTVITY

TREATMENT GROUP B

	SBL 1 Obsevation1		SBL 2 Observation 2		SBL 3 Observation 3		SBL 4 Observation 4	
Patient	Factor Score	Mean Score	Factor Score	Mean Score	Factor Score	Mean Score	Factor Score	Mean Score
TR4	**19**	3.17	**18**	3.00	**17**	2.83	**15**	2.50
TR5	14	2.33	13	2.17	13	2.17	18	3.00
TR8	17	2.83	18	3.00	20	3.33	12	2.00
TR12	9	1.50	13	2.17	14	2.33	13	2.17
TR13	17	2.83	17	2.83	15	2.50	10	1.67
TR14	10	1.67	17	2.83	11	1.83	19	3.17
TR17	12	2.00	12	2.00	11	1.83	12	2.00
TR19	17	2.83	16	2.67	16	2.67	17	2.83
TR20	15	2.50	13	2.17	15	2.50	14	2.33
TR21	20	3.33	17	2.83	17	2.83	15	2.50
Average	15.00	2.50	15.40	2.57	14.90	2.48	14.50	2.42

APPENDIX N
Letter addressed to schools

Gauteng Schools
Johannesburg
2001
August 2003

57 Tunny Street
Groeneweide
Elspark
1423

Dear Headmaster/Headmistress:

RE: ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD) RESEARCH

I am a homeopathic master's student of Durban Institute of Technology.

Certain pupils at your school have been recruited for a clinical trial, the title being: **The relative efficacy of Advanced Brain Food® and a Homeopathic Preparation (Quietude®) in the management of ADHD of school-going boys between the ages of 8 and 13 years.**

The study will involve the following procedures:

- Boys between the ages of 8 and 13 will be the main focus of this trial.
- These children must be pre-diagnosed as having ADHD.
- For the purpose of this trial that will last for 6 weeks, these children will not be allowed to take any allopathic medication (e.g. Ritalin®) as stipulated in the selection criteria of this particular trial.
- Before being accepted into the trial the child's parent/guardian will be required to complete an informed consent form, and the child will need to complete an informed assent form.
- It is important to state that a child can withdraw from the study at any time without giving a reason.

Should you require any further information please do not hesitate to contact my supervisor or me at any time.

Thank you for your co-operation regarding this matter.

Yours Sincerely,

John-John Lottering.
(Final year Homeopathy Student)
Cell: 084 555 9977

Dr. Leon Strauss
(Supervisor)
Cell:082 330 3966

APPENDIX O4

ADHD RATING SCALE-IV (DU PAUL, 1998)

TOTAL OF SCORES OBTAINED FOR INNATENION AND HYPERACTIVITY (Obser. 1-4)

	TEST 1 RESULT			TEST 2 RESULT			TEST 3 RESULT			TEST 4 RESULT		
PATIENT	IA TEST	HI TEST	**TOTAL**	IA TEST	HI TEST	**TOTAL**	IA TEST	HI TEST	**TOTAL**	IA TEST	HI TEST	**TOTAL**
TR1	13	12	**25**	23	18	**41**	24	18	**42**	16	16	**32**
TR3	19	15	**34**	11	13	**24**	9	12	**21**	9	9	**18**
TR4	10	8	**18**	11	7	**18**	7	11	**18**	7	11	**18**
TR5	15	18	**33**	15	14	**29**	19	16	**35**	18	20	**38**
TR6	16	19	**35**	18	19	**37**	19	18	**37**	14	12	**26**
TR7	9	11	**20**	13	11	**24**	9	12	**21**	12	11	**23**
TR8	24	25	**49**	23	23	**46**	17	17	**34**	18	19	**37**
TR9	15	15	**30**	19	17	**36**	18	19	**37**	15	17	**32**
TR10	15	12	**27**	18	15	**33**	17	15	**32**	20	16	**36**
TR11	14	10	**24**	11	11	**22**	15	15	**30**	15	16	**31**
TR12	16	10	**26**	15	16	**31**	22	14	**36**	17	20	**37**
TR13	12	4	**16**	17	17	**34**	17	12	**29**	15	16	**31**
TR14	20	25	**45**	15	21	**36**	15	18	**33**	11	14	**25**
TR15	13	10	**23**	17	20	**37**	15	13	**28**	15	9	**24**
TR16	14	18	**32**	9	14	**23**	16	11	**27**	14	16	**30**
TR17	23	26	**49**	21	20	**41**	16	17	**33**	16	15	**31**
TR18	23	20	**43**	17	16	**33**	10	13	**23**	15	11	**26**
TR19	25	20	**45**	10	10	**20**	18	17	**35**	17	11	**28**
TR20	22	24	**46**	21	19	**40**	21	18	**39**	21	23	**44**
TR21	7	3	**10**	7	7	**14**	9	10	**19**	7	5	**12**

APPENDIX P

Health history

First name _____ Surname _____

Vaccinations and dates _____

Past illnesses and age _____

Hospitilisation _____

Current medication _____

Allergies (including any drug allergies or reactions to medications)

Birth history (please include type of birth, any complications at birth or during pregnancy and any illnesses during the pregnancy).

Family history of illness (allergies, diabetes, heart disease, high blood pressure, mental illness, cancer, tuberculosis, porphyria, etc.).

Mother _____

Father _____

APPENDIX P (CONTINUED)

Grandparents (M) _____

Grandparents (F) _____

Brother/ s _____

Sister/ s _____

Average daily diet (please include snacks and drinks as well as your child' s favourite foods, sweets, drinks and anything he/ she craves).

Breakfast _____

Lunch _____

Supper _____

Snacks/ drinks _____

Parental concerns

What are your concerns about your child? _____

What do you see as your child' s strengths? _____

What have you been told by doctors, teachers and/ or others about your child' s condition that concerns you?

_____

APPENDIX Q4

ADHD RATING SCALE-IV (DU PAUL, 1998)

TOTAL OF SCORES OBTAINED FOR INNATENION AND HYPERACTIVITY (Obser. 1-4)

	TEST 1 RESULT			TEST 2 RESULT			TEST 3 RESULT			TE
PATIENT	IA TEST	HI TEST	**TOTAL**	IA TEST	HI TEST	**TOTAL**	IA TEST	HI TEST	**TOTAL**	IA TEST
TR1	13	12	**25**	23	18	**41**	24	18	**42**	16
TR3	19	15	**34**	11	13	**24**	9	12	**21**	9
TR4	10	8	**18**	11	7	**18**	7	11	**18**	7
TR5	15	18	**33**	15	14	**29**	19	16	**35**	18
TR6	16	19	**35**	18	19	**37**	19	18	**37**	14
TR7	9	11	**20**	13	11	**24**	9	12	**21**	12
TR8	24	25	**49**	23	23	**46**	17	17	**34**	18
TR9	15	15	**30**	19	17	**36**	18	19	**37**	15
TR10	15	12	**27**	18	15	**33**	17	15	**32**	20
TR11	14	10	**24**	11	11	**22**	15	15	**30**	15
TR12	16	10	**26**	15	16	**31**	22	14	**36**	17
TR13	12	4	**16**	17	17	**34**	17	12	**29**	15
TR14	20	25	**45**	15	21	**36**	15	18	**33**	11
TR15	13	10	**23**	17	20	**37**	15	13	**28**	15
TR16	14	18	**32**	9	14	**23**	16	11	**27**	14
TR17	23	26	**49**	21	20	**41**	16	17	**33**	16
TR18	23	20	**43**	17	16	**33**	10	13	**23**	15
TR19	25	20	**45**	10	10	**20**	18	17	**35**	17
TR20	22	24	**46**	21	19	**40**	21	18	**39**	21
TR21	7	3	**10**	7	7	**14**	9	10	**19**	7

APPENDIX Q2

MEAN SCORES AND TOTALS OBTAINED- INNATENTION (OBSERVATION 1-4)

PATIENT	OBSERVATION 1			OBSERVATION 2			OBSERVATION 3			OBSERVATION 4		
	MEAN HI	MEAN IA	TOTAL SCORE	MEAN HI	MEAN IA	TOTAL SCORE	MEAN HI	MEAN IA	TOTAL SCORE	MEAN HI	MEAN IA	TOTAL SCORE
TR1	1.33	1.44	**2.77**	2	2.56	**4.56**	2	2.67	**4.67**		1.78	**1.78**
TR3	1.67	2.11	**3.78**	1.44	1.22	**2.66**	1.33	1	**2.33**		1	**1**
TR4	0.89	1.11	**2**	0.78	1.22	**2**	1.22	0.78	**2**		1.22	**1.22**
TR5	2	1.67	**3.67**	1.56	1.67	**3.23**	1.78	2.11	**3.89**		2.22	**2.22**
TR6	2.11	1.78	**3.89**	2.11	2	**4.11**	2	2.11	**4.11**		1.33	**1.33**
TR7	1.22	1	**2.22**	1.22	1.44	**2.66**	1.33	1	**2.33**		1.22	**1.22**
TR8	2.78	2.67	**5.45**	2.56	2.56	**5.12**	1.89	1.89	**3.78**		2.11	**2.11**
TR9	1.67	1.67	**3.34**	1.89	2.11	**4**	2.11	2	**4.11**		1.89	**1.89**
TR10	1.33	1.67	**3**	1.67	2	**3.67**	1.67	1.89	**3.56**		1.78	**1.78**
TR11	1.11	1.56	**2.67**	1.22	1.22	**2.44**	1.67	1.67	**3.34**		1.78	**1.78**
TR12	1.11	1.78	**2.89**	1.78	1.67	**3.45**	1.56	2.44	**4**		2.22	**2.22**
TR13	0.44	1.33	**1.77**	1.89	1.89	**3.78**	1.33	1.89	**3.22**		1.78	**1.78**
TR14	2.78	2.22	**5**	2.33	1.67	**4**	2	1.67	**3.67**		1.56	**1.56**
TR15	1.11	1.44	**2.55**	2.22	1.89	**4.11**	1.44	1.67	**3.11**		1	**1**
TR16	2	1.56	**3.56**	1.56	1	**2.56**	1.22	1.78	**3**		1.78	**1.78**
TR17	2.89	2.56	**5.45**	2.22	2.33	**4.55**	1.89	1.78	**3.67**		1.67	**1.67**
TR18	2.22	2.56	**4.78**	1.78	1.89	**3.67**	1.44	1.11	**2.55**		1.22	**1.22**
TR19	2.22	2.78	**5**	1.11	1.11	**2.22**	1.89	2	**3.89**		1.22	**1.22**
TR20	2.67	2.44	**5.11**	2.11	2.33	**4.44**	2	2.33	**4.33**		2.56	**2.56**
TR21	0.33	0.78	**1.11**	0.78	0.78	**1.56**	1.11	1	**2.11**		0.56	**0.56**

APPENDIX Q3

ADHD RATING SCALE-IV (DU PAUL, 1998)

TOTAL RESULTS FOR HYPERACTIVITY/ INNATENTION

PATIENT	SCORE Obs. 1	MEAN SCORE 1	SCORE Obs. 2	MEAN SCORE 2	SCORE Obs. 3	MEAN SCORE 3	SCORE Obs. 4	MEAN SCORE	TOTAL MEAN SCORE (Obs.1-4)
TR1	12	**1.33**	18	**2.00**	18	**2.00**	16	**1.78**	14.78
TR3	15	**1.67**	13	**1.44**	12	**1.33**	9	**1.00**	9.86
TR4	8	**0.89**	7	**0.78**	11	**1.22**	11	**1.22**	8.28
TR5	18	**2.00**	14	**1.56**	16	**1.78**	20	**2.22**	14.39
TR6	19	**2.11**	19	**2.11**	18	**2.00**	12	**1.33**	14.14
TR7	11	**1.22**	11	**1.22**	12	**1.33**	11	**1.22**	9.75
TR8	25	**2.78**	23	**2.56**	17	**1.89**	19	**2.11**	17.08
TR9	15	**1.67**	17	**1.89**	19	**2.11**	17	**1.89**	15.14
TR10	12	**1.33**	15	**1.67**	15	**1.67**	16	**1.78**	13.11
TR11	10	**1.11**	11	**1.22**	15	**1.67**	16	**1.78**	11.94
TR12	10	**1.11**	16	**1.78**	14	**1.56**	20	**2.22**	14.17
TR13	4	**0.44**	17	**1.89**	12	**1.33**	16	**1.78**	12.61
TR14	25	**2.78**	21	**2.33**	18	**2.00**	14	**1.56**	15.42
TR15	10	**1.11**	20	**2.22**	13	**1.44**	9	**1.00**	11.94
TR16	18	**2.00**	14	**1.56**	11	**1.22**	16	**1.78**	11.89
TR17	26	**2.89**	20	**2.22**	17	**1.89**	15	**1.67**	15.17
TR18	20	**2.22**	16	**1.78**	13	**1.44**	11	**1.22**	11.67
TR19	20	**2.22**	10	**1.11**	17	**1.89**	11	**1.22**	11.11
TR20	24	**2.67**	19	**2.11**	18	**2.00**	23	**2.56**	17.33
TR21	3	**0.33**	7	**0.78**	10	**1.11**	5	**0.56**	6.19
TOTAL	305	**33.89**	308	**34.22**	296	**32.89**	287	**31.89**	

APPENDIX Q4

ADHD RATING SCALE-IV (DU PAUL, 1998)

TOTAL RESULTS FOR INNATENTION

PATIENT	SCORE Obs. 1	MEAN SCORE 1	SCORE Obs. 2	MEAN SCORE 2	SCORE Obs. 3	MEAN SCORE 3	SCORE Obs. 4	MEAN SCORE	TOTAL MEAN SCORE (Obs.1-4)
TR1	13	**1.44**	23	**2.56**	24	**2.67**	16	**1.78**	17.86
TR3	19	**2.11**	11	**1.22**	9	**1.00**	9	**1.00**	8.58
TR4	10	**1.11**	11	**1.22**	7	**0.78**	7	**0.78**	7.22
TR5	15	**1.67**	15	**1.67**	19	**2.11**	18	**2.00**	14.86
TR6	16	**1.78**	18	**2.00**	19	**2.11**	14	**1.56**	14.61
TR7	9	**1.00**	13	**1.44**	9	**1.00**	12	**1.33**	9.69
TR8	24	**2.67**	23	**2.56**	17	**1.89**	18	**2.00**	16.78
TR9	15	**1.67**	19	**2.11**	18	**2.00**	15	**1.67**	14.86
TR10	15	**1.67**	18	**2.00**	17	**1.89**	20	**2.22**	15.69
TR11	14	**1.56**	11	**1.22**	15	**1.67**	15	**1.67**	11.78
TR12	16	**1.78**	15	**1.67**	22	**2.44**	17	**1.89**	15.44
TR13	12	**1.33**	17	**1.89**	17	**1.89**	15	**1.67**	13.94
TR14	20	**2.22**	15	**1.67**	15	**1.67**	11	**1.22**	11.94
TR15	13	**1.44**	17	**1.89**	15	**1.67**	15	**1.67**	13.42
TR16	14	**1.56**	9	**1.00**	16	**1.78**	14	**1.56**	11.22
TR17	23	**2.56**	21	**2.33**	16	**1.78**	16	**1.78**	15.36
TR18	23	**2.56**	17	**1.89**	10	**1.11**	15	**1.67**	12.31
TR19	25	**2.78**	10	**1.11**	18	**2.00**	17	**1.89**	13.19
TR20	22	**2.44**	21	**2.33**	21	**2.33**	21	**2.33**	18.11
TR21	7	**0.78**	7	**0.78**	9	**1.00**	7	**0.78**	6.58
TOTAL	325	**36.11**	311	**34.56**	313	**34.78**	292	**32.44**	