A pilot study on the efficacy of *Valeriana officinalis* mother tincture and *Valeriana officinalis* 3X in the treatment of attention deficit hyperactivity disorder

**Introduction**

**Problem statement**

**Aim of the study**

The aim of this three-week, double-blind, placebo-controlled pilot study was to determine the efficacy of homeopathic *Valeriana officinalis* mother tincture (MT) and 3X potency on attention deficit hyperactivity disorder (ADHD).

**Background**

As a behavioural disorder, ADHD is characterised by inattention, impulsivity and hyperactivity (Mosby’s Medical Dictionary 2009). The incidence of ADHD is on the increase (Clarke, Barry, McCarthy & Selikowitz 2002:276–286), with around 3% – 9% of children worldwide exhibiting...
Valeriana officinalis is indicated mainly for symptoms such as restlessness (Boericke 2005:509; Smith, Terre Blanche & Weyand 2001:665, 1100). More than half of all childhood cases continue into adulthood (Wilens 2008). Multiple aetiologies have been described over several years, including genetic and biochemical causes; however, research to establish a clear cause continues (Beers, Berkwits, Jones, Kaplan & Porter 2006).

ADHD is diagnosed according to the criteria set out in the Diagnostic & Statistical Manual for Mental Disorders (DSM-IV-TR) (American Psychiatric Association 2000), which identifies three types of ADHD: ADHD, predominantly inattentive type, ADHD-predominantly hyperactive-impulsive type and ADHD, combined type. The main treatments advised for ADHD are medication, behavioural interventions and educational accommodations (DuPaul & Weyandt 2006:341–358). Stimulants, such as Ritalin® and Concerta® appear to increase intrasynaptic catecholamines (mainly dopamine and norepinephrine) in the brain (Wilens 2008) and are thought to stimulate the part of the brain responsible for inhibiting behaviour and maintaining effort or attention to objects (Barkley 2005:323, 327). Whilst these medications are effective in improving ADHD symptoms in most children (Barkley 2005:323, 327), as many as 20% – 30% of children either do not respond to this class of drug or cannot tolerate them (Wilens 2008). Stimulants may produce many short-term and long-term adverse effects, such as insomnia, anxiety, aggression (Picton 2005), suppression of growth and cardiovascular effects (Barkley 1998:57–186; DrugLib.com n.d.; Fox 1997:705, 936). Strattera®, a non-stimulant drug, has been shown to improve ADHD symptoms (National Institute of Mental Health 2006); however, it can also increase suicidal tendencies (Aschenbrenner 2006:33).

Mother tinctures (MTs) are liquid preparations resulting from the extraction of living source material with alcohol and water mixtures and are produced in accordance with homeopathic pharmacopoeia standards (Kayne 1997:90). Homeopathic MT preparations of Valeriana officinalis differ from conventional botanical preparations in that the MT is made only from fresh plant tissue, in a 1:10 ratio, whereas botanical preparations may be prepared from dried or fresh plant tissue and are usually in a 1:5 ratio (Bilia, Eterno, Bergonzi, Mazzi & Vinci 2007:70–78). Thus, in fact, a MT = 1D or 1X (10% strength). As a homeopathic remedy, Valeriana officinalis is indicated mainly for symptoms such as impatience, irritability and inattention (Vermeulen 1997:1631–1634) and may be helpful in treating someone experiencing nervous restlessness, a desire for activity and a changeable disposition. All symptoms are worse for sitting or standing still and better for motion (Vermeulen 2001:178–9; Frei et al. 2005:509; Smith, Terre Blanche & Solomon 2001). Valerian (Valeriana officinalis) is a botanical medicine that has a powerful effect on the nervous system and displays calming and antispasmodic properties (Grieve 2003). It has been found to be beneficial in the treatment of disorders such as anxiety and insomnia (Balch 2002:138–139; Hobbs 1993:6, 20) and, more recently, ADHD and other similar disorders characterised by restlessness (Berdonnes 2001:11–14; Blumenthal 1998). For identification and quality control, one of its main active compounds, valeranic acid, is used as a marker (Koetter 2009:154–166). Valeranic acid inhibits the breakdown of gamma aminobutyric acid (GABA) in the central nervous system, an action similar to that of benzodiazepine drugs (Kemper 1999; Murphy, Kubin, Shepherd & Ettinger 2009). Valerian is typically used as a tea, tincture, or an extract produced with an alcohol and water mixture and is known to have an intense odour (Koetter 2009:154–166). The European Scientific Cooperative on Phytotherapy approves of the use of valerian for children aged three to 12 years, under medical supervision (Kemper 1999).

Research objectives

Although Valerian is generally considered safe (Kemper, Gardiner & Chan 2000:116), there are, however, no studies that have specifically evaluated its efficacy in children and, to date, no controlled clinical trials have evaluated its use in treating ADHD (Kemper 1999). Also, whilst Valeriana officinalis has been used clinically by homeopaths for children with ADHD, its efficacy in treating this condition when prepared as a MT and a 3X potency has not been researched.

Contribution to the field

This study has contributed to our knowledge on the use of Valeriana officinalis as an alternative treatment intervention in the management of children with ADHD.

Research method and design

Design

This was a double-blind, placebo-controlled study involving 30 participants between the ages of five and 11 years. Approval and ethical clearance for the study was obtained from the Technikon Witwatersrand Faculty Research Committee.

Data collection methods

Participants were recruited by means of advertisements placed in the newsletters of schools in the urban and rural areas of Gauteng Province, South Africa. Meetings to discuss the study procedure were held with the respective headmasters and guidance teachers of each school which took part in the study. Participants had to be pre-diagnosed
with ADHD, combined type, and have no evidence of any other medical or neurological disease. Participants could not be on any form of medication for ADHD. The study procedure was discussed with each parent or guardian and teacher and an information sheet was issued outlining the important points of the study. The parents or guardians of the participants were required to sign a consent form and, in addition, were asked not to introduce any measures that would benefit the child’s ADHD during the study, for example, dietary changes, nutritional or herbal supplements, or known ADHD medication.

The participants were randomly assigned to either the experimental groups or the control group and thus 10 children received *Valeriana officinalis* MT, 10 received *Valeriana officinalis* 3X and 10 received a placebo. Accordingly, groups were not matched for baseline differences at the start of the study. The medication was prepared in 50ml amber glass bottles and was randomised, packaged and labelled by Natura Laboratories. The same batch of *Valeriana officinalis* was used to make the medication and Natura Laboratories tested batches for purity and the presence of active ingredients. Because *Valeriana officinalis* MT is a strong-tasting and strong-smelling liquid, Natura standardised the medication by adding natural caramel to the MT, 3X and placebo, to make all three medicines taste the same and attempt to mask the smell of the MT. As natural caramel was used, the symptoms of ADHD were not expected to be affected. The parents or guardians were asked to administer 10 drops, three times a day after meals, for two weeks. Even though the children’s ages ranged from five to 11 years, a dose of 10 drops was recommended for all, as this is the standard dosage schedule advised for children of less than 12 years of age. All parents or guardians, participants, observers and raters were blinded with regard to the nature of the medication received by each child.

Assessment of the participants was carried out using the Barkley and DuPaul teacher rating scale, the children’s checking task (CCT), and Conner’s parent symptom questionnaires (PSQ), which were completed by the teacher, the child and the parent or guardian, respectively. The Barkley and DuPaul teacher rating scale contains 14 school-related questions, which have the rating options not at all, just a little, pretty much, and very much, with respective scores of 0, 1, 2 and 3 points. This test is used to obtain information about the child’s current academic and behavioural problems (Barkley 1998:510–526; DuPaul 1991:245–253). The CCT is a paper-and-pencil activity consisting of four pages of vigilance tasks, which assess the child’s ability to sustain attention and which measure motor-visual skills (Schain & Oetinger 1978:210). Participants were shown how to complete the CCT. The children were then asked to complete the ‘practise page’ before commencing with the actual test. This ensured that the children clearly understood the requirements of the CCT. These tests were completed and timed, under the supervision of the researcher (Nichols & Waschbusch 2004:297–315). Conner’s PSQ consists of a 48-item scale grouped into six categories, namely: conduct problems; inattention; psychosomatic problems; impulsivity and/or hyperactivity; anxiety and hyperactivity index. Each item is rated in the same manner as the teacher rating scales (Goyette, Conners & Ulrich 1978). The parent or guardian of each participant completed the PSQ. Subjective observations of the child’s behaviour were made and discussed.

These assessments were completed on four occasions, namely, before the study commenced (the first consultation), at week one after the treatment had been administered (the first follow-up) and at week two after the treatment had been administered (the second follow-up). The participants were instructed to stop treatment administration in the third week of the study and complete the assessments following one week of no administration (the third follow-up). The final test scores were compared with the first test scores (the scores prior to treatment) to determine the efficacy of *Valeriana officinalis* MT and *Valeriana officinalis* 3X. The third follow-up determined whether the effects produced by *Valeriana officinalis* MT and *Valeriana officinalis* 3X had lasted one week following no treatment administration.

**Data analysis**

The raw data obtained from assessments one, two, three and four were statistically analysed by comparing the scores obtained before, during and after the trial for the medication and placebo groups. The data obtained from the PSQ, the teacher rating scale and the CCT were analysed using the paired t-test and analysis of variance (ANOVA).

**Context of the study**

This study was conducted at various primary schools in Gauteng, with necessary permission granted by all parties.

**Results**

Twenty-seven participants (18 boys and 9 girls) completed the study, with a gender proportion which is consistent with the trend in ADHD cases, namely, a gender distribution of 2:1 in favour of boys (Barkley 1998:510–526). Three participants did not complete the study: one from the placebo group and two from the experimental group. The ages of the participants varied from five to 11 years, with an average age of 7.93 years. For analysis purposes, the categories were divided into Test 1 (the before test), Test 2 and Test 3 (the during tests), and Test 4 (the after test), which represented the three-week study period. Within each of these test categories, the average values and scores of the three treatment groups were compared. Baseline differences did occur between the control group and the experimental groups. These differences occurred because randomisation, per definition, was the result of chance.

**Parent symptom questionnaire results**

The PSQ results have been divided into their respective categories and are discussed individually below. Lower average-value scores represent an improvement in symptoms...
recorded in the PSQ. The ANOVA results revealed no statistical significance overall between Valeriana officinalis MT and Valeriana officinalis 3X; however, the placebo group scored significantly poorer results overall than the experimental groups.

**Hyperactivity index**

Table 1 shows a significant reduction \( (p = 0.040) \) in hyperactivity after one week of treatment for the experimental groups and a highly significant improvement \( (p < 0.001) \) was revealed for both the experimental groups and the placebo group after two weeks of treatment. These effects were not maintained after one week of no treatment administration.

**Conduct problems**

With regard to conduct problems, the change was not significant \( (p > 0.100) \) for either the placebo group or the experimental groups.

**Inattention**

Analysis of this category of symptoms revealed a highly significant improvement for the experimental groups \( (p = 0.008) \) and the placebo group \( (p = 0.010) \) after two weeks of administration (Table 2). Although Valeriana officinalis 3X continued to have an effect following one week of no treatment administration, the effects produced by Valeriana officinalis MT and the placebo, respectively, diminished during this time.

**Psychosomatic problems**

A comparison of Test 1 and Test 3 revealed a significant improvement \( (p = 0.017) \) for the placebo group after two weeks of administration. No significant improvement was recorded for the experimental groups.

**Impulsivity and/or hyperactivity**

An extremely significant reduction \( (p < 0.001) \) in symptoms such as restless, in the squirmy sense and restless, always up and on the go was recorded for both the experimental groups and the placebo group after the first week of administration, continuing into the second week of study (Table 3). The effects produced by all three groups were maintained following one week of no treatment administration. These effects were not recorded for the experimental groups.

**Anxiety**

Analysis revealed a significant improvement \( (p = 0.014) \) in this category for the experimental group following two weeks of treatment. This was, however, followed by an increase in the average-value scores in both experimental remedies after one week of administration. No significant improvement \( (p > 0.100) \) occurred in the placebo group.

**Children’s checking task results**

These results were divided into total scores and speed scores categories. Higher average-value scores for the total scores category indicated a better result scored by the participants, given in percentages. Lower average-value scores for the speed scores category for each treatment indicated a reduction in the time taken to complete the CCT. The ANOVA results illustrated no significant difference overall between Valeriana officinalis MT and Valeriana officinalis 3X; however, the placebo group scored significantly poorer results than the experimental groups.

**Total scores**

Following two weeks of treatment, the experimental groups showed a highly significant improvement \( (p = 0.007) \) in their ability to complete the CCT accurately. The improvement continued following one week of no treatment administration. There was no significant improvement for the control group \( (p > 0.100) \).

**Speed scores**

When Test 1 was compared with Test 2, a significant improvement \( (p = 0.015) \) was recorded for the experimental groups and when Test 1 was compared with Test 3, a highly significant improvement \( (p = 0.007) \) was seen. These positive results continued into the final week, following one week of no treatment administration. There was no significant improvement for the control group \( (p = 0.550) \).

**Barkley and DuPaul teacher rating scale results**

In order to determine the differences between the three treatment groups, the 14 questions in the teacher rating scale were grouped together and the total scores were analysed using ANOVA. Lower average-value scores represented a reduction in the symptoms of the participants, as recorded by the teachers involved.

Analysis of the 14 questions revealed a significant improvement \( (p < 0.0500) \) in nine of the 14 questions,
especially noticeable following two weeks of treatment in the experimental groups. Particular improvement was observed for the experimental groups in the symptoms often fidgets or squirms in seat (p = 0.0001), is easily distracted (p = 0.0070), has difficulty playing quietly (p = 0.0090), often does not seem to listen (p = 0.0080), and has difficulty sustaining attention to tasks (p = 0.0020).

The ANOVA results revealed no statistical significance overall between Valeriana officinalis MT and Valeriana officinalis 3X (Table 4). The placebo group showed a statistically significant improvement in only two of the 14 symptoms and overall scored significantly poorer results than the experimental groups.

Ethical considerations
This research was approved (Ethical Clearance Number: TWR FRC 22/08/2002) by the Faculty Research Committee of the Faculty of Health Sciences of the Technikon Witwatersrand on 22 August 2002.

Informed consent
Participation in the study was voluntary. The parents or guardians of the participants were required to sign an information- and consent form. Children assented to participation in the study. All procedures were explained in detail in the information sheet and participants and their parents or guardians were informed of their rights. There were no anticipated risks to the study. They were ensured of the utmost privacy and all consultations took place in a private consultation area. Confidentiality was maintained and protected both during and after the research study by replacing names with case numbers and all case files were locked away in a secure filing cabinet.

Trustworthiness
Validity and reliability
There are numerous rating scales available for the diagnosis and assessment of ADHD children. Rating scales such as the Barkley and DuPaul teacher rating scale, the CCT and the PSQ are quick, easy and cost-effective methods of gathering information from the home and school environment. These scales allow for parents and teachers to provide information in a clear and concise manner. Parental ratings have been shown to be a reliable source of information, as parents are likely to be more familiar with a child’s history and current situation and can highlight strengths and weaknesses that may not be elicited by standard psychometric tests. Teacher rating scales are also an important part of evaluating ADHD children as teachers are able to evaluate children in a school setting and judge their behaviour in the context of their peers. All rating scales available may show age, gender and race bias and may constitute problems with reliability and validity; however, when combining multiple aspects of evaluation, rating scales have proven to be a useful tool in establishing the presence and severity of ADHD symptoms and their statistical divergence from normal children (Cordes & McLaughlin 2004:23–29).

<table>
<thead>
<tr>
<th>Test</th>
<th>Average Value</th>
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<tbody>
<tr>
<td>MT</td>
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<tr>
<td></td>
<td>20.25</td>
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<td></td>
<td>18.38</td>
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<td></td>
<td>19.75</td>
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<td></td>
<td>19.00</td>
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<td></td>
<td>18.56</td>
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<tr>
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<td></td>
<td>22.78</td>
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<td></td>
<td>22.11</td>
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<td></td>
<td>23.89</td>
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MT, Valeriana officinalis mother tincture; 3X, Valeriana officinalis 3X potency.

TABLE 4: Comparison of the mean teacher rating scale total score results for the three test groups across the study period.

Discussion
Parent symptom questionnaire
According to the statistical analysis, most of the PSQ categories significantly improved following two weeks of treatment. Valeriana officinalis is known to treat symptoms of inattention and hyperactivity and it therefore follows that improvement was noted in the categories of hyperactivity, inattention and impulsivity and/or hyperactivity. These results verify the potential use of Valeriana officinalis in attention and hyperactivity difficulties, two of its major indications. The MT and 3X groups also illustrated a statistically significant improvement in the symptom of anxiety, which is significant, as Valeriana officinalis is known to have anxiolytic properties. The category of conduct problems did not improve as significantly as did the other PSQ categories. The presence of the symptoms outlined in this category may indicate the presence of co-morbid conditions such as conduct disorder or oppositional defiant disorder. Valeriana officinalis is not typically indicated for these conditions. Should homeopathic remedies be implemented in the treatment of such disorders, higher strengths, or potencies, should perhaps be considered.

Children’s checking task
The CCT analysis showed a significant improvement in the second week of treatment in both total scores and speed scores, illustrating an overall improvement in sustained attention. With each progressive test, the participants may have become accustomed to the contents and patterns of the test, resulting in their scoring higher marks and being able to complete the test faster. The experimental groups, however, did significantly outperform the placebo group.
Barkley and DuPaul teacher rating scale

The teacher rating scale analysis revealed a trend similar to that seen in the PSQ and CCT. Particular improvement was observed in the symptoms *often fidgets or squirms in seat, is easily distracted, often does not seem to listen, has difficulty playing quietly, and has difficulty sustaining attention to tasks*. These symptoms also pertain to hyperactivity and inattention, which are symptoms apt to being treated by *Valeriana officinalis*. Nine of the fourteen questions in the questionnaire showed a significant improvement, which was especially noticeable following two weeks of treatment. The placebo group showed a statistically significant improvement in only two of the 14 symptoms.

Although Boericke (2001:665, 1100) claims that *Valeriana officinalis* has a lasting duration of eight to 10 days following discontinuation of treatment, this was not found to be the case in this particular study, with many symptoms reappearing in the last week, following no treatment administration.

Limitations of the study

Throughout the study there was a recurrent tendency for the placebo group to show a decrease in symptoms, with significant changes seen in the PSQ results. This *placebo effect* may have occurred because environmental factors such as the parent-child relationship serve as determinants of severity, co-morbidity and prognosis (Barkley 2005:510–526). When children are introduced to new management strategies at the same time that the parents are, as was the case in this study, it is easier for the parent to work with the child, as the child becomes more cooperative (Power, Russell, Sofer, Blom-Hoffman & Grim 2002:117–126). The physiological response to the medication may also have been unintentionally facilitated, as the participants could have exhibited a *meaning response* to the empathetic researcher (Frenkel 2008:58–79). Thus the *placebo response* to the medication in combination with the *meaning response* to the researcher, parents or guardians and teachers, could have resulted in this effect being seen. Overall, the positive effects produced by all three treatment groups were not maintained following one week of no administration. Because the medication was not being administered during this time, the *new management strategies* were no longer being employed and, consequently, the child became less cooperative again in response to receiving less attention. Behavioural interventions or modifications in the parent-child relationship may have affected the treatment used in the study. Baseline differences for the three groups should have been assessed at the start of the study. It was determined that the symptoms of the placebo group were worse at baseline. This might have resulted in a regression, where the mean biased the results against a true effect being found. Matched pairs, according to severity, would have overcome this limitation.

Recommendations

Further studies could include a comparison between the effects of medication and the effects of behaviour modification procedures. Higher potencies may prove to be more beneficial and faster-acting. Most of the children in the study found that the remedies were foul-tasting, despite the addition of caramel, making the administration of the medication problematic for the parents. The use of medicated, lactose-based tablets in follow-up studies is recommended. Future studies could also make use of more updated methods of assessing inattention and impulsivity, such as Conner’s parent and teacher rating scale and Conner’s continuous performance test.

Further studies concerning *Valeriana officinalis* should be conducted over a longer period of time, as additional improvement may be observed after two weeks of treatment. One study conducted in children with restlessness and insomnia suggested that there was greater symptom improvement after four weeks of continuous use of valerian, regardless of the dosage prescribed (European Medicines Agency 2007:16).

Conclusion

Attention deficit hyperactivity disorder is an increasingly prevalent childhood behavioural disorder, with the onset of symptoms normally occurring before the age of seven years (Mosby’s Medical Dictionary 2009). The symptoms of inattention, hyperactivity and impulsivity can affect the child’s social, behavioural and academic functioning (Clarke et al. 2002). *Valeriana officinalis* is indicated for conditions characterised by nervous system hyperexcitability (Vermeulen 1997:1631–1634). *Valeriana officinalis* MT and *Valeriana officinalis* 3X were used in this study and a statistically significant improvement was found in the behaviour of the treatment groups according to the scores recorded for the PSQ, the teacher rating scale and the CCT. These improvements were especially noticeable after two weeks of treatment, with particular reference to sustained attention, anxiety and impulsivity and/or hyperactivity. This reflects a possible time-dependent or dose-response relationship. No statistically significant difference was observed between the MT potency and the 3X potency. The positive effects produced in the first two weeks of the study were not maintained overall following one week of no administration. The preliminary findings of this pilot study indicate the positive role of *Valeriana officinalis* in the management of ADHD and clearly support the importance of further research. The effect of *Valeriana officinalis* on ADHD should be investigated over a longer period of time, in a higher potency, and using a larger sample group.

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Competing interests
The authors declare that they have no financial or personal relationships which may have inappropriately influenced them in writing this article.

Authors’ contributions
S.J.W. (University of Johannesburg) was the project coordinator and was responsible for experimental and project design. R.R. (University of Johannesburg) and J.P. (University of Johannesburg) wrote the manuscript.

References