CHAPTER THREE: MATERIALS AND METHODOLOGY

3.1. RESEARCH DESIGN

The research study was a double-blind placebo-controlled clinical trial without crossover, involving thirty participants.

3.2. METHODOLOGY

The following steps were carried out over the course of the clinical trial:

- Thirty subjects were recruited by approaching various schools north of Johannesburg. Advertisements (refer to Appendix A) of the study were placed in the newsletters of the respective schools, and posters advertising the study were posted up at libraries, sports clubs and recreation centres in the area. Meetings were held with the respective heads and guidance teachers of the schools to discuss the clinical trial procedure.

- Respondents who met the requirements set out in 3.2.1 below were asked to take part in the study.

- A meeting was held with the parent/s and teacher of each prospective participant to discuss the trial procedure. An information sheet (refer to Appendix B) outlining the important points of the study was provided for the parents, and the trial procedure was explained. Parents were required to sign a consent form (refer to Appendix C), and was made aware of their right to discontinue treatment at any time. Parents were asked not to introduce any additional medication or supplements, nor to change their child's diet over the course of the trial.

- The 50ml amber glass bottles of medication were labelled at Natura laboratories using random numbering. The subjects were then randomly provided with a bottle of medication that blindly and randomly assigned them to either the experimental or control group. Thus, fifteen children received *Phosphorus* 6CH (experimental group) and fifteen received a placebo standardised in smell, taste, and appearance

identically with the medication by Natura laboratories (control group). Dosage instructions and manner of handling homoeopathic medications was demonstrated.

- The teachers of the subjects involved received the Barkley and DuPaul Teacher Rating Scale (BDTRS) (refer to Appendix D) which formed the subjective assessment of the subjects. An appropriate Children's Checking Task (CCT) (refer to Appendix E for CCT1 and Appendix F for CCT2) consisting of four pages of vigilance tasks was used to assess the ability of the children to sustain attention and measured motor-visual skills (Schain and Oetinger, 1978:210) and was completed during class time in order to objectively assess the subjects. The teachers received instructions from the researcher explaining how these tests should be performed.

- The parent of each subject was required to complete the Parents Symptom Questionnaire (PSQ) (see Appendix G) and was instructed on how to do this. Parents, teachers, and children completed their weekly forms on the same day.

- The treatment period was carried out over three weeks, as recommended by Natura laboratories. The first assessment was conducted before the treatment commenced, and the second and third assessments weekly after treatment had begun. A fourth assessment was done a week after treatment had been completed to ascertain whether the effects of the treatment lingered. Teachers and parents were contacted over the course of the treatment period to clarify any problems. The set of results was collected after the trial period.

- During the trial, participants were handled anonymously. Following the trial period a meeting was held with the parents of the respective children and the results discussed. Further treatment options were discussed with the parents.

- Using paired t-tests, the second and third weeks' test scores were compared to the first to determine the efficacy of *Phosphorus* 6CH in the management of ADHD. The fourth weeks' scores were compared to the third weeks' to establish whether *Phosphorus* 6CH maintained its efficacy after cessation of treatment.

- Results from the placebo group and the experimental group were then compared from these tests.

3.3. SUBJECTS

Thirty subjects completed the study of which sixteen were boys and fourteen were girls. This gender proportion is in accordance with Faller's suggestion in 2002 that the normal gender distribution of ADHD for boys and girls is close to 1:1. Subjects were residents of northern Gauteng, and from a broad spectrum of socio-economic grouping. All thirty children completed the study, with all forms being filled out and returned. Weekly telephone calls were made to both parents and teachers to remind them to complete the forms and to clarify any concerns or queries.

The following criteria had to be met in order for a child to be eligible for the study:

- Subjects had to be between four and eleven years of age.
- Subjects had to have been pre-diagnosed with ADHD (or given a deferred diagnosis of ADHD) and not have evidence of another medical or neurological disease.
- Subjects could not be on any form of medication for ADHD.
- Parental permission in the form of a signed consent form had to be obtained before the subject could participate in the study.
- Parents had to be willing not to make any significant changes to the subjects diet or allow additional medication to be taken for the duration of the study.

3.4. ADMINISTRATION OF THE TREATMENT

Parents and guardians were asked to administer the medication at a dosage of ten drops three times a day continuously for two weeks. The parents (and teachers if necessary) were asked to ensure administration of the treatment fifteen minutes after breakfast, lunch and supper.

Phosphorus 6CH is a simplex homoeopathic preparation manufactured by Natura Laboratories in Pretoria. The product (application number U1555) is awaiting registration with the Medical Controls Council (MCC) according to Act 101 of 1965.

3.5. ASSESSMENT TOOLS

The assessment tools used in this study were based on those used in similar studies conducted by Meyer (2001) and Smith (2001). The researcher remained in contact with the parents and teachers during the clinical trial period to exclude patient non-compliance.

3.5.1. Barkley and DuPaul Teachers' Rating Scale

The Barkley and DuPaul Teachers' Rating Scale was completed weekly by the class teacher of each participant. This scale is similar to the Conner's Abbreviated Teacher Rating Scale used in by Meyer (2001), Smith (2001) and Strauss (1998) in previous homoeopathic research into ADHD.

Fourteen observable behaviours were rated and scores allocated to each rating as follows:

- Not at all = 0
- A little = 1
- Pretty much = 2
- Very much = 3

After completion of the clinical trial, weekly evaluations were compared to establish the pattern of behaviour observed by the teacher during this time. These results were statistically analysed using paired t-tests to determine if a significant difference between results was present. The results of the experimental and placebo groups were then compared.

3.5.2. Children's Checking Task

Two Children's Checking Task (CCT) papers were used during this study. They were assigned to each child according to the school grade level of the child. CCT1 (refer to Appendix E) was used for the younger children (pre-school children), while CCT2 (refer to Appendix F) was used for school-going children. Interpreters were used to explain the tests to any children for whom English was not a first language.

A stopwatch was used to establish the time taken by the child to complete the entire CCT. Times were compared at the end of the clinical trial to establish whether children managed to complete the work in a significantly better time frame than in the initial week.

Each CCT comprises four pages of vigilance tasks. The first page is a practice sheet to ensure that the child understands the instructions correctly. Each page consists of a number of blocks, each main block consisting of a random assortment of numbers, letters, symbols, or words, and a target block with the target number, letter, symbol, or word at the top of the main block.

3.5.3. Parent Symptom Questionnaire

The Parent Symptom Questionnaire required the parent of each participant in the study to rate forty-eight symptoms according to the following scale:

- Not at all = 0
- Just a little = 1
- Pretty much = 2
- Very much = 3

These forty-eight symptoms were then assigned to six categories (refer to Table 3.1) and scores calculated for each category. Category scores over the four weeks of the clinical trial were then statistically compared and analysed to determine if a significant differences were found. The results of the experimental and placebo groups were then compared.

Table 3.1. Parent Symptom Questionnaire (PSQ) Categories

Category	**PSQ Symptoms**
Conduct Problems	2, 3, 8, 14, 15, 17, 19, 20, 21, 22, 23, 27, 29, 33, 34, 35, 36, 39, 45, 46
Inattention	9, 10, 25, 31, 37
Psychosomatic Problems	32, 40, 41, 42, 43, 44, 48
Impulsivity/ Hyperactivity	1, 4, 5, 11, 13, 28
Anxiety	6, 12, 16, 18, 24, 26, 30, 47
Hyperactivity Index	4, 7, 11, 13, 14, 25, 31, 33, 37, 38

3.6. DATA COLLECTION AND ANALYSIS

The raw data obtained from the research study was collected, and the results were statistically analysed using the paired t-test. Results were initially analysed by means of descriptive statistics, and the means and standard deviations for the experimental and control groups reported.

The alpha value of significance was set at 0.05 and therefore P-values were classified as follows:

- $P>0.1$ = not significant
- $P<0.1$ = not quite significant
- $P<0.05$ = significant
- $P<0.01$ = very significant
- $P<0.001$ = extremely significant

Results were analysed and conclusions drawn as to their significance.