

**The efficacy of homoeopathic similimum in the  
treatment of nocturnal enuresis in children  
between five and eighteen years who reside in  
children's homes.**

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I Michael Bloch, declare that this dissertation represents my own work, both in  
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## **Dedications**

### **Ruth Bloch**

This thesis represents the end of a five- year degree, which would not have been possible without my mother support on many levels. I am humbled by the example that she has set for me as a mother, an individual and a homoeopath.

### **The Children**

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Dr B has been our family homoeopath for as long as I can remember. She is also the "mother" of homoeopathy in South Africa having taught many of our teachers. I celebrate her grace and dignity.

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## ABSTRACT

This study was intended to evaluate the efficacy of homoeopathic similimum in the treatment of nocturnal enuresis. It was part of a group research project, which explored the effectiveness of a homoeopathic complex (Cantharis vesicatoris 12ch, Equisetum hyemale 12ch, Sarsaparilla 12ch, Staphisagria 12ch, Uva ursi 12ch) as well as Ilex paraguayensis 6x in the treatment of the above-mentioned disorder. The sample group consisted of children between the ages of five and eighteen living in various children's homes in Durban.

Nocturnal enuresis is categorised into primary and secondary types. Primary nocturnal enuresis is the failure to achieve consistent dryness, whereas secondary nocturnal enuresis is the return of nocturnal incontinence after an extended period. For the purpose of this study this distinction was largely ignored, as homoeopathic treatment is not reliant on a detailed diagnosis for its efficacy. The children were however screened for chronic urinary tract infections as well as neurological and systemic causes of nocturnal enuresis. Each child received a full physical examination as well as an extensive homoeopathic interview. The aim of this was to exclude any clear aetiology as well as to glean the information necessary to establish the homoeopathic similimum.

The sample size for this trial was 32 children; sixteen received similimum and formed the treatment group, and a further sixteen received placebo and formed

the placebo group. The clinical trial commenced after the initial consultation and lasted eight weeks. The first two weeks were an observation period used to establish a base line for statistical analysis. The following two weeks formed the treatment period where each child received a single powder dose each evening before bed. The last four weeks were a post treatment observation period. During these eight weeks enuresis diaries were filled in by the care givers'. This information i.e. number of wet nights per week, was used for statistical analysis. Upon completion of the trial the group of children who received placebo were offered free treatment, and those who wished to continue with treatment were referred to the homoeopathic day clinic at the Durban Institute of Technology.

The decision to carry out this trial was based on the high incidence of nocturnal enuresis in children's homes, and the need to address this problem. In addition the literature search found an absence of any homoeopathic placebo-controlled trials. There was, however, an abundance of anecdotal evidence in the form of cured cases as well as a number of books containing clinical information. This suggested a need to contribute to the body of homoeopathic literature with regards to this subject.

The results were analysed at a 95% confidence level as follows:

- The average number of wet nights for each group was calculated.
- The Wilcoxon's Signed Rank test was used to evaluate improvement within each group.

- The Mann-Whitney U test was used to compare the groups.
- The improvement was calculated on the percentage difference in number of wet nights between the baseline period and the rest of the trial.

The statistical analysis of the trial produced promising results. The placebo group showed little statistically significant intra-group improvement in the post-treatment period ( $p=0.139$ ). There was a 12.5 - 18.75% improvement for this group. The treatment group however showed statistically significant improvement for the same period ( $p=0.017$ ), with an improvement of 25 -37.5%. The results for all extra-group comparisons were statistically insignificant. This implied that although a statistically significant improvement occurred in the treatment group, it was insubstantial in comparison to the placebo group. Regardless of this the results point toward improvement especially due to the fact that only a single treatment was offered and that the trial involved children with traumatic backgrounds. The homes involved in this study provide a necessary safety net for children who have been abused, traumatised and abandoned. In addition the conditions at the homes are often far from ideal due to financial constraints. Although harsh, this is the background against which this research is set. It is the researcher's contention that similar trials over a longer period of time would yield even better results.

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## DEFINITION OF TERMS

### Homoeopathy

Homoeopathy as defined by Swayne (2000:105) is a "therapeutic method using preparations of substances whose effects when administered to healthy subjects correspond to the manifestations of the disorder (symptoms, clinical signs, pathological states) in the individual patient. The method was developed by Samuel Hahnemann (1755-1843)".

Implicit to this method are three fundamental principles. (1) Similia Similibus Curentur (let likes be cured by likes) (Hahnemann, 1997:48). "This is the fundamental principle of homoeopathy which states that substances may be used to treat disorders whose manifestations are similar to those which they will themselves manifest in healthy subjects" (Swayne, 2000:193). These manifestations in healthy people are determined by the use of provings and subsequent clinical verification. (2) The use of homoeopathically prepared remedies i.e. medicine specially prepared through a process of serial dilution and succussion, trituration or fluxion (Swayne, 2000:169). (3) Individualisation - "The art of selecting the homoeopathic prescription that corresponds to the particular manifestation of the illness in the patient rather than on the common characteristics of the disorder itself" (Swayne, 2000:112).

## **Similimum**

Swayne (2000:194) defines the similimum as the drug picture most like the clinical picture in the patient. It is arrived at through careful analysis of information found in the homoeopathic case record.

## **Nosode**

Medicine which is "derived from pathological material", and prepared according to homeopathic principles. "It may be of human, animal or plant origin, including micro-organisms, diseased tissue, or the products of disease processes" (Swayne, 2000:145).

## **Remedy**

For the purposes of this trial a remedy will be considered to be a medicine prepared according to homoeopathic principles. On a broader level it may be considered as any treatment aimed at a condition, whether specific or not.

## **Repertory**

According to Swayne (2000: 183) this is defined as "a systematic cross reference of symptoms and disorders to the homoeopathic medicines in whose therapeutic



repertoire (materia medica) they occur. The strength or degree of the association between the two is indicated by the type in which the medicine name is printed ". It is alternatively defined as "a source used in case analysis to identify the remedy indicated for the patient. This process is called repertorisation".

### **Rubric**

"The phrase used in a repertory to identify a symptom or disorder and its component elements and details, and categories of these, and to which a list of the medicines which are known to have produced that symptom or disorder in homoeopathic pathogenetic trials, or to have remedied it in clinical practice, is attached" (Swayne 2000: 186).

### **Enuresis**

Enuresis may be defined as involuntary discharge of urine after the age by which bladder control should have been established usually five years (Ullom-Minnich, 1996:2259).

### **Nocturnal enuresis**

Nocturnal enuresis is described by Norgaard et al. (1998:1) as the voiding of urine in bed at night without the child noticing it.

### **Primary nocturnal enuresis**

Primary nocturnal enuresis is the failure to achieve dryness consistently at night and accounts for more than 90 percent of cases (Ullom-Minnich, 1996:2259).

According to the Diagnostic and Statistical Manual of Mental Disorders the following criteria need to be met (DSM 4-R, 307.6).

- Repeated voiding of urine into bed or clothes (whether intentional or involuntary).
- The behaviour is significant as manifest either by a frequency of twice a week for at least three consecutive months or the presence of clinically significant distress or impairment in social, academic (occupational), or other important areas of functioning.
- Chronological age is at least 5 years (or equivalent developmental level).
- The behaviour is not due exclusively to the direct physiological effect of a substance (e.g. a diuretic) or a general medical condition (e.g. spina bifida, a seizure disorder, diabetes) (DSM-4, 1995:109).

### **Secondary nocturnal enuresis**

Secondary enuresis refers to the return of incontinence at night after an extended period of dryness. It should include an extended period of dryness of 6 months or more (Ullom-Minnich, 1996:2259).

## **Placebo**

Dorland's dictionary (1989) defines a placebo as a "procedure with no intrinsic value performed in controlled studies to determine the effect of treatment". A more modern definition by Morris and Shapiro (as cited by Ernzt, 2001:18) is "any therapy or component of therapy that is used for its non-specific psychological or psychophysiological effect".

## **Nocebo**

Nocebo effects are the adverse effects that can occur after the administration of a placebo (Ernzt, 2001:21).

## **Placebo group**

The group of subjects in a clinical trial that receive a non-specific treatment i.e. a placebo. Traditionally this group is used as a measure against which treatment is compared.

## **Treatment group**

The group of subjects in a clinical trial who receive treatment that is specific for a given condition.

## Success

Success in this trial will be considered a 50% reduction in bedwetting.

## CHAPTER 1

### INTRODUCTION

The word "enuresis" originates from the Greek word "enourein" - to void urine. Nocturnal enuresis in children is described by Norgaard et al. (1998:1) as the voiding of urine in bed at night without the child noticing it. This problem has perplexed many over centuries with medical literature dating back to the Papyrus Ebers of 1550 BC (cited by Grobler, 1996:1). It is a highly prevalent disorder affecting 15-20% of children at the age of five with a typical remission rate of 15% per annum (Marla et al. 1996:2259).

Traditionally nocturnal enuresis is divided into primary and secondary types.

Primary enuresis is the failure to achieve dryness consistently" whereas secondary enuresis refers to the return of incontinence after an extended period of dryness (Ullom-Minnich, 1996:2259). Inherent to both of these definitions is the absence of a recognisable anatomical, neurological or urological causes e.g. diabetes mellitus, cystitis, spina bifida.

Despite extensive research a clear causative mechanism has yet to be established. The prominent theories include developmental delay, genetics, sleep disorders, behaviour and psychogenic disorders, constipation and increased diuresis at night due to low levels of antidiuretic hormone (Cendron, 1999:2).

In turn the current trends in treating the condition are aimed at drugs that can influence the above causes. The most common drugs include Imipramine hydrochloride (brand name Tofranil ®), an antidepressant; Oxybutin chloride (brand name Ditropan ®) an antispasmodic agent; and Desmopressin acetate (DVAVP), a synthetic antidiuretic hormone (Cendron, 1999: 9; Ullom-Minnich, 1996: 2264; Lackgren et al., 1988). The use of allopathic medication is however not without complication due to short-term effectiveness, side effects and cost. In addition to drug therapy non-pharmacological treatment is available in the form of alarm systems, bladder stretching, hypnosis, dry bed training, chiropractics and acupuncture (Ullom-Minnich, 1996; Grobler, 1996). Despite these treatments there remains an absence of any one approach that offers a total cure.

There is extensive anecdotal evidence indicating that homoeopathic treatment is effective in treating bedwetting. Numerous respected authors e.g. Farrington (1950), Lilienthal (1969), Ghegas (1988), Imhauser (1988) etc. suggest various remedies and approaches based on their clinical experience. In addition there are various journal articles presenting cured cases (Popescu (1998), Jaiswall (1989), Klunker (1989)). There is however a paucity of material validating the homoeopathic approach in terms of double blind clinical trials.

### **1.1 Problem statement**

This study proposed to evaluate the efficacy of homoeopathic similimum

in the treatment of nocturnal enuresis with regard to the number of wet nights per week. It focussed on children between the ages of five and eighteen, residing at children's homes in the greater Durban area. The data (wet nights per week) was statistically analysed using three procedures.

Objective one: The first objective proposed to evaluate the response of the treatment group to homoeopathic similimum in order to evaluate the role this treatment played in the management of nocturnal enuresis. Wilcoxon's signed rank test was used to compare intra-group data in the treatment group (statistical procedure 1).

Objective two: This objective proposed to evaluate the response of the placebo group to placebo in order to evaluate the role this treatment played in the management of nocturnal enuresis. Wilcoxon's signed rank test was used to compare intra- group data in the placebo group (statistical procedure 2).

Objective three: This objective proposed to integrate the results of the placebo and treatment groups in order to determine the efficacy of the homoeopathic similimum in the management of this condition. Mann Whitney U test was used for extra-group comparisons (statistical procedure 3).

This study therefore proposed to investigate the efficacy of the homoeopathic similimum in the treatment of nocturnal enuresis. The researcher hoped that the study would demonstrate the efficacy of the homoeopathic similimum as an effective and safe alternative to existing treatment protocols.

## CHAPTER 2

### REVIEW OF THE RELATED LITERATURE

#### 2.1 Introduction

The following discussion focuses on literature related to nocturnal enuresis. It seeks to explore the current understanding of the subject in terms of aetiology, prevalence, physiology and management.

#### 2.2 Definition

Enuresis may be defined as involuntary discharge of urine after the age by which bladder control should have been established usually five years (Ullom-Minnich, 1996:2259). Nocturnal enuresis is described by Norgaard et al. (1998:1) as the voiding of urine in bed at night without the child noticing it.

Most authors further subdivide enuresis into primary and secondary types.

Primary enuresis is the failure to achieve dryness consistently and accounts for more than 90 percent whereas secondary enuresis refers to the return of incontinence after an extended period of dryness (Ullom-Minnich, 1996:2259). Norgaard et al. (1998:2) suggest that secondary enuresis should include an extended period of dryness of 6 months or more.



According to Medel et al. (1998:50) nocturnal enuresis should be further classified into monosymptomatic and complicated types depending on whether bedwetting is the only symptom or is associated with urinary tract infections, diurnal incontinence or urgency.

Thus for the purposes of this research monosymptomatic primary and secondary enuresis will be considered thereby separating children with a definable aetiology from those without. Nocturnal enuresis is considered to be functional in the absence of any underlying cause (Medel et al., 1998:51).

### **2.3 Anatomy and physiology of the bladder**

The bladder is a hollow muscular vesicle for the storage of urine. In adults the empty bladder is located in the pelvic minor, posterior and slightly superior to the pubic bone. It only enters the abdomen when distended with the exception of infants. In infants the bladder is located in the abdomen and only enters the pelvic minor at about the age of six. The bladder is characterised by its distensibility, with its shape, size and position varying according to urine content and age (Moore, 1985:269).

The bladder is a smooth muscular chamber composed of two parts: (1) the body in which the urine collects and (2) the neck which passes inferiorly to the urethra. The smooth muscle of the bladder is known as the detrusor muscle.

The bladder contains an external and internal sphincter. The internal sphincter is often referred to as the bladder neck and is located in the region of entry of the ureters. Its natural tone keeps the neck and posterior urethra empty and thus helps prevent emptying of the bladder until the pressure in the body reaches a critical threshold. The external sphincter in contrast to the internal sphincter is composed of voluntary muscle and is under the control of the central nervous system (Guyton, 1992: 243-244).

### **2.3.1 Innervation of the bladder**

The bladder receives its innervation from the visceral plexus, which has both parasympathetic and sympathetic components. The sympathetic component, which is derived from T11-L2, reaches the bladder via the hypogastric nerve and is inhibitory. The parasympathetic supply is derived from S2-S4 and reaches the bladder via the pelvic splanchnic nerve. These fibres are motor to the detrusor muscle and inhibitory to the internal sphincter. Thus when these fibres are stimulated by stretching, the bladder contracts and the internal sphincter relaxes allowing urine to enter the urethra (Moore, 1985: 269,; Guyton, 1992: 243-244).

### 2.3.2 Micturition process and reflex

Micturition is the process by which a full bladder empties itself. It is initiated by a micturition reflex that occurs when tension in the bladder wall rises above a threshold value. As the bladder fills a series of micturition contractions begin to occur due to activation of the stretch receptors in the bladder wall. Sensory information is passed from the receptors via the pelvic nerves to the sacral section of the spinal cord and then back again via the parasympathetic fibres. These signals cause progressive contractions of the bladder wall, which are self-regenerative. This means that as the bladder contracts the stretch receptors are further stimulated thereby causing subsequent waves of contraction. This occurs until a strong degree of contraction occurs when yet another reflex takes place (Guyton, 1992: 244-245).

This reflex passes via the pudendal nerves and inhibits the external sphincter allowing micturition to occur. This however only takes place if the inhibition to the external sphincter is more powerful than the voluntary constrictor signals from the brain. Once the micturition reflex has occurred but the bladder is not emptied the reflex lies in an inhibited state for a few hours to a few minutes depending on the bladder content (Guyton, 1992: 244-245).

### **2.3.3 Control of micturition by the brain**

The micturition reflex is an automatic cord reflex, which can be inhibited by the brain. This occurs via the facilitatory and inhibitory centers in brain stem and other centers in the cortex. Although the micturition reflex is the basic cause of micturition, the higher centers can exert final control by the following means.

- The higher centers keep the reflex partially inhibited at all times except when micturition is desired.
- The higher centers can prevent micturition despite the reflex by tonic contraction of the external sphincter.
- The cortical centers can help initiate a micturition reflex as well as inhibit the external sphincter (Guyton, 1992: 245).

### **2.4 Epidemiology**

There are no recent epidemiological studies in South Africa on the subject of enuresis. According to Grobler, (1996:13) a study by De Jong (1988) suggested a prevalence of 28% in the Durban region. Authors from various texts concur with Marla et al. (1996:2259) that 10-20% of 5 year olds, 5-7% of 10 year olds and 2-4% of 12 to 14 year old children are affected. Cendron and Klauber (1998:26) report a spontaneous resolution rate of 15%, which is

supported by other authors. Cendron (1999:2) further states that an estimated 5 to 7 million children are affected in the United States. The above figures suggest a notable prevalence despite the lack of local verification.

The incidence at various children's homes in Durban is high and varies from home to home depending on the ages that they accommodate. Although not quantifiable, nocturnal enuresis was identified as one of the major health problems by these homes (Govender, 2001). Whether this is a function of the conglomeration of children at the homes or an issue of institutionalisation can only be determined by extensive local prevalence studies.

## **2.5 Aetiology**

The aetiology of primary nocturnal enuresis has been widely debated but is not yet completely understood. Primary nocturnal enuresis is a diagnosis of exclusion and all other known causes must be ruled out (Cendron, 1999:2).

The aetiology of primary nocturnal enuresis remains somewhat controversial (Ullom-Minnich, 1996: 2259), and the condition appears to be multifactorial (Cendron, 1999:2). Possible aetiologies of primary nocturnal enuresis include developmental delay, genetics, sleep disorders, psychogenic disorders (Cendron, 1999:2), constipation, increased diuresis at night due to low levels of antidiuretic hormone and reduced functional bladder capacity (Ullom-Minnich, 1996:2259).

The theory of nocturnal diuresis supports the use of synthetic anti-diuretic hormone for treatment. It is based on the concept that insufficient antidiuretic hormone (vasopressin) is produced during sleep with a resultant over production of urine that exceeds the bladder's capacity. The production of antidiuretic hormone is theoretically controlled by a diurnal cycle, with an increased production at night thereby inhibiting the formation of urine. The absence or irregularity of such a cycle is thought to be an aetiological factor (Cendron, 1999:2., Ullom-Minnich, 1996:2259).

The presence of developmental delay is a commonly accepted cause of bedwetting. A delayed functional maturation of the central nervous system reduces the child's ability to inhibit bladder emptying at night. It results from the inability of the higher cortical functions to exert control over the external sphincter as described in section 2.3.3 (Cendron, 1992:2).

Genetics have long been accepted as a causative factor. Cendron (1999:2) cites studies that report various incidences. In one study, children whose parents had a history of bedwetting showed a 77% incidence. This was seen in contrast to a 44% incidence in children who had a single parent who was enuretic and a 15% incidence in those with an absence of parental history.

An old theory was that enuretics had some form of sleep disorder. It was hypothesised that enuretics spent more time in deep sleep and were harder to arouse from sleep. Recent sleep studies have disproved this and suggest that enuresis is related to the phases of sleep. Thus if 40% of the time is spent in

delta sleep and 30% of the time in rapid eye movement sleep (REM) then 40% of incidences would occur during delta sleep and 30% in REM sleep. In addition sleep studies have not been able to discern any difference in the sleep pattern between enuretic and non-enuretic children (Ullom-Minnich, 1996:2259).

Studies on bladder capacity have found that enuretic and non-enuretic children have the same bladder capacity. It has however been demonstrated that the functional bladder capacity of enuretics is less i.e. the amount of urine voided after micturition has been postponed for as long as possible. The hypothesis is that enuretic children feel the urge to urinate when there is a small volume of urine in the bladder. In other words there is an earlier triggering of the micturition reflex (Ullom-Minnich, 1996:2260). This work supports the use of "bladder stretching" as a form of treatment.

Psychological stresses have long been implicated in nocturnal enuresis. It is thought that such stresses are significant in children with secondary enuresis but are of little note in children with primary enuresis. It is however recognised that emotional problems can occur as a result of parental or other responses. Cendron (1999:1) supports these ideas and also quotes various studies. One study in New Zealand used a population-based model and followed children up to the age of fifteen. Using specific psychiatric criteria they concluded that there was little or no difference in the behaviour between enuretic and non-enuretic subjects. Another study in Denmark reported a poor sense of belonging to society as well as significantly reduced self-esteem in enuretics.

According to Rosenfeld (as cited by Grobler, 1996:16) stress during critical times of learning or development may affect normal development of bladder and bowel control. He also states that there is a higher incidence of bedwetting in children from broken homes and in children who have had traumatic separations from family members. Furthermore bedwetting often forms part of the symptom complex in children with psychiatric or psychological problems.

Causes of secondary enuresis include neurogenic bladder and associated spinal cord abnormalities, urinary tract infections, and the presence of posterior urethral valves in boys or an ectopic ureter in girls. Posterior urethra valves cause significant voiding symptoms, such as straining to void and diminished urinary stream whereas an ectopic ureter causes constant wetting (Cendron, 1999:2). The above causes are clearly diagnosable, they however do not imply that all secondary nocturnal enuresis is due to an identifiable cause. Rather secondary nocturnal enuresis needs to be carefully investigated; in the absence of an identifiable cause the aetiology is thought to be the same as primary nocturnal enuresis (Marla, 1996:2261).

## **2.6 Treatment**

### **2.6.1 Introduction**

The treatment of and therapeutic approach to nocturnal enuresis is complicated by the multifactoral nature of the condition, lack of a clear



aetiology and pathophysiological understanding of the condition (Cendron, 1999: 2). The current treatment can be divided into two broad categories, pharmacological and non-pharmacological.

## **2.6.2 Pharmacological treatment**

### **2.6.2.1 Imipramine hydrochloride**

This drug has been used for approximately 25 years. It is thought to alter the sleep and arousal mechanism, affect sympathetic nerve supply to the bladder, increase the secretion of anti-diuretic hormone or a combination of these (Cendron, 1999: 9). Success rates range from 25 to 50% with a 30% relapse rate (Ullom-minnich, 1996: 2259). Side effects are common and range from insomnia to personality changes and nervousness as well as the danger of overdose (Cendron, 1999: 9).

### **2.6.2.2 Anticholinergic therapy**

Studies done on the effectiveness of Oxybutynin and Hyoscymine are limited. They appear to act on smooth muscle, decreasing the bladder's capacity to contract (Ullom-Minnich, 1996: 2264). Side effects range from constipation to dizziness and tremors (Cendron, 1999: 9). Cendron and Klauber (1998) demonstrated a 60% success rate in a study using Hyoscymine and Desmopressin combined. The relapse rate however was high, pointing to palliation rather than cure.

### **2.6.2.3 Desmopressin Acetate (DDAVP)**

This drug is an anti-diuretic, decreasing urine production at night by raising anti-diuretic hormone levels. The success rate varies between studies, but all confirm limited if any side effects. Desmopressin is fast acting and thus useful in cases of parental intolerance or to avoid embarrassment if a child is sleeping away from home. In a 7 year follow up study on the effect of Desmopressin, Lackgren et al. (1998) demonstrated a significant cure rate, which was maintained after the termination of therapy. The cure rate could have been affected by the children outgrowing bedwetting naturally, or as a result of the attention they received. It is presently the drug of choice (Lackgren et al., 1998). Some of the side effects include weight gain, convulsions, coma, headaches, allergic skin reactions and serum sodium loss if there is not a restricted water intake (Snyman, 1999: 187).

### **2.6.3 Non-pharmacological treatment**

According to Ullom-Minnich (1996), non-pharmacological treatments are usually used in combination with one another or in conjunction with pharmacological treatments. Ullom-Minnich (1996) evaluates each approach. The alarm system is approximately 70% effective with a relapse rate of 30%. Bladder stretching, in which the child has to withhold urination for increasing amounts of time has an improvement rate of 60% but is time consuming and requires motivation. Dry bed training, which includes night waking, cleanliness

training, positive practice and the alarm has a 85 to 100% success rate and is considered a good treatment option. Hypnosis has a 40 to 70% success rate but is expensive.

The mentioned treatment approaches and modalities are influenced by the patient's family environment and by the background and prejudices of the patient, the parents and the physician (Cendron, 1999:2). No treatment as yet offers a total and lasting cure.

## **2.7 Homeoeopathy and the similimum**

Homeoeopathy as defined by Swayne (2000:105) is a "therapeutic method using preparations of substances whose effects when administered to healthy subjects corresponds to the manifestations of the disorder (symptoms, clinical signs, pathological states) in the individual patient. The method was developed by Samuel Hahnemann (1755-1843)". Implicit to this method are three fundamental principles:

(1) Similia Similibus Curentur (let likes be cured by likes) (Hahnemann, 1997:48). "This is the fundamental principle of homeoeopathy which states that substances may be used to treat disorders whose manifestations are similar to those which they will themselves manifest in healthy subjects" (Swayne, 2001:193). These manifestations in healthy people are determined by the use of provings (homeopathic drug trials) and subsequent clinical verification of the information.

(2) The use of homoeopathic remedies i.e. medicine specially prepared through a process of serial dilution and succussion, trituration or fluxion (Swayne, 2001:169).

(3) Individualisation - " The art of selecting the homoeopathic prescription that corresponds to the particular manifestation of the illness in the patient rather than on the common characteristics of the disorder itself" (Swayne, 2001:112).

The ultimate aim of the homoeopathic enquiry and analysis is to arrive at the similimum. Swayne (2000:194) defines the similimum as the drug picture most like the clinical picture in the patient. It is arrived at through careful analysis of information found in the homoeopathic case record using the above concept of individualisation.

Watson (1991:90) expands upon this idea saying that in order to individualise one has to choose characteristic symptoms. These according to Hahnemann (1997:169) are the "more striking, exceptional, unusual, and odd symptoms". Thus unlike the allopathic approach where diagnostic criteria are of prime importance, the homoeopathic approach seeks to understand an individual's particular expression of their disease (De Schepper, 1999:42). In keeping with this idea, information which is considered useless to an allopathic diagnosis is vital to the homoeopathic enquiry as it expresses the unique characteristics of how a person manifests disease (De Schepper, 1999:43). These

manifestations are expressed on mental, emotional and physical planes and need to be understood in a hierarchical manner (Vithoulkas, 1978:39). The mental and emotional planes represent the higher functions and are thus more important than physical characteristics in terms of a hierarchy.

Vithoulkas draws these well accepted homoeopathic ideas from Hahnemann who stressed the importance of the patient's mental and emotional state (Hahnemann, 1997:197). This however does not preclude the value of peculiar or characteristic physical symptoms. This can be understood by studying various clinical texts that describe such symptoms (Farrington (1950), Lilienthal (1969), Imhauser (1980) etc).

There is a paucity of homoeopathic literature on the treatment of enuresis. The Glasgow homoeopathic library database contains 42 entries dating back to 1908 under the broad category of enuresis. To date no double-blinded clinical trial has been found suggesting the efficacy of this approach. However a number of articles present individual cured cases (Popescu, 1998., Jaiswal., 1989., Klunker, 1989).

Unlike the limited pharmacological approach to treatment described earlier, homoeopathy has a number of drugs that may be employed in bedwetting (Sharma, 1995:29). In addition to Sharma's drug descriptions the Complete Repertory (Van Zandvoort, 2000) lists over 120 drugs in the rubric urination involuntary; night. The differentiation in use is based on a careful analysis of

the case including causative factors, time modality and mental temperament (Jaswal, 1989:333).

Popescu (1989:103-106) clearly describes this approach in his cases. Although he has found major polycrests to be useful e.g. *Calcarea carbonica*, *Pulsatilla pratensis* etc. he emphasises the need for individualisation. He also asserts that in the absence of any pathological cause the homoeopathic enquiry should be psychosomatic. To this extent he feels that the "causa occasionalis" should be carefully investigated e.g. psychological conflicts, moral shocks, frights (apprehension) and jealousy.

Agrawal (1994:31-340) presents an overview of the homoeopathic approach to urinary diseases. In the section on enuresis he encourages the use of behaviour modification and restraint from punishing behaviour. He presents an extensive list of remedies and their characteristic symptoms in enuresis and stresses the need for individualisation. He suggests that special attention is given to odour of urine, sleep position, temperament and time of occurrence (e.g. first sleep) during case taking.

Chandra (1986:62-63) reports an interesting case of nocturnal enuresis in a 10-year old girl. The most important idea in his article is that a number of remedies were tried, and failed until a peculiar symptom was identified (fear of her own shadow). This then led them to the similimum which was curative.

Goel (1996:7-8) describes two cured cases of nocturnal enuresis. His approach is to establish the characteristic symptoms through careful case taking. This includes the patient's medical history, family history, temperament, food desires and cravings, temperature modalities and other concomitant illnesses. He prescribed nosodes for both of these cases, with a resultant cure of the patients' main and secondary complaints.

Koirellim (1976:25-26) cites Tyler's pointers to common remedies in nocturnal enuresis. He also recommends a practical approach to the problem in addition to homoeopathic treatment. This includes establishing causation e.g. is the child afraid of the dark, using reward systems, avoiding humiliation of the child and counselling the parents. His perspective is that in the absence of an identifiable cause, bedwetting is a social problem.

## **2.8 Placebo**

A placebo as defined by Dorland's dictionary (1989) is a "procedure with no intrinsic value performed in controlled studies to determine the effect of treatment". A more modern definition by Morris and Shapiro (as cited by Ernzt, 2001:18) is "any therapy or component of therapy that is used for its non-specific psychological or pyscophysiological effect". The difference

between these definitions is that the one focuses on being a neutral control whereas the other recognises a therapeutic effect.

According to Peters (2001:2) 60% of placebo groups tend to improve, forcing us to re-evaluate the placebo effect. This can be described as the difference in outcome between a placebo treated group and an untreated group in an unbiased experiment (Ernzt, 2001:18). The effect of placebos is powerful; examples as cited by Hawkins (2001:72) include (1) the use of saline injection for acute head pain, (2) the placebo component of anti-depressants being nearly twice as powerful as the pharmacological component, (3) the 2.5 time greater death rate over a years follow up for post-myocardial infarction patients who took little of their prescribed placebo medicine as compared to those who took it regularly. Another interesting example cited by Reilly (2001:101) is a single blind trial where the four participants received placebo treatment and were followed up with either placebo or active treatment. All four patients responded in significantly different ways.

The significance of this discussion is to recognise that a placebo control group is not neutral. Rather the use of placebo is a form of treatment as may be demonstrated by trial outcomes. Nonetheless the use of placebo controlled groups in trials is a useful method of comparing and ascertaining outcomes (Ernzt, 2001:25).



There are a number of factors that contribute to the placebo effect. These include the (1) nature of the intervention e.g. injections vs. pills, the use of hi-tech approaches (ultra sound), the colour of the medication or the unusual nature of a therapeutic encounter (homoeopathic consultation). (2) The nature of the therapist e.g. confidence, demeanour, empathy, warmth, reputation and prestige. (3) The time factor involved - the longer the consultation the better the placebo effect. (4) The patient, their trust in the therapist and their worldviews. (5) The nature of the complaint. (6) The therapeutic setting (Ernzt, 2001:28).

As it can be seen there are a number of factors that can influence the action of a placebo. These must be taken into account when designing and evaluating the outcome of a trial.

## **2.9 Conclusion**

Nocturnal enuresis is a perplexing and prevalent disorder. The allopathic approach is limited with regard to its understanding of aetiology and treatment. Despite the absence of clinical trials, the available literature is suggestive of the efficacy of the homoeopathic similimum in the treatment of this condition.

## **CHAPTER 3**

### **MATERIALS AND METHODS**

#### **3.1 The objective / problem statement**

This study proposed to evaluate the efficacy of homeopathic similimum in the treatment of nocturnal enuresis with regard to the number of wet nights per week. It focussed on children between five and eighteen.

The objective is to assess the role this treatment has to play in the management of this condition in children residing in children's homes.

#### **3.2 The Data**

Primary and secondary data were utilised in this study. The primary data is represented by the number of wet nights the subjects presented with over an eight week period, as well as the medical records of each subject.

The secondary data was obtained from the available literature on enuresis, as well as information sourced from the Internet.

#### **3.3 The Research Methodology**

### **3.3.1 Research Design**

This research is part of a larger group project that comprises of three different components (homoeopathic similimum, homoeopathic complex (Cantharis vesicatoris 12ch, Equisetum hyemnale 12ch, Sarsaparilla 12ch, Staphisagria 12ch, Uva ursi 12ch) and Ilex paraguayensis 6x). Each component has applied a different approach to the same problem i.e. the treatment of nocturnal enuresis. This research concerns itself with the use of homoeopathic similimum. The clinical trials for the above three approaches were simultaneously run and share a collective placebo group. The results for each component are independently documented.

### **3.3.2 Subjects**

The subjects for this research were obtained by approaching children s homes in the local Durban area. All the subjects were between five and eighteen years old and resided at the above homes. All subjects had to meet the inclusion criteria (see pg. 23).

### **3.3.3 Sample**

Twenty-one children participated in the trial; 5 received placebo and 16 received homoeopathic similimum. The overall study comprised of 66 children divided into three groups of 22, with the minimum objective being to have three treatment groups of 15 and a collective placebo group of 15. Due to

excellent compliance at the various homes a final collective placebo group of 16 members was identified. All the children who received homoeopathic similimum completed the trial. Thus for statistical analysis both the placebo and treatment group number 16 members.

### **3.3.4 Inclusion criteria**

- Subjects had to be between the ages of five and eighteen years.
- Subjects were considered for the study if they met the DSM 4-R (307.6) criteria.
  - A. Repeated voiding of urine into bed or clothes, (whether intentional or involuntary).
  - B. The behaviour is significant as manifest by either a frequency of twice a week for at least three consecutive months or the presence of clinically significant distress or impairment in social, academic (occupational), or other important areas of functioning.
  - C. Chronological age is at least 5 years (or equivalent developmental level).
  - D. The behaviour is not due exclusively to the direct physiological effect of a substance (e.g., a diuretic) or a general medical condition (e.g. spina bifida, a seizure disorder, diabetes) (DSM-4, 1995:109).
- Subjects were included in the study once they and their guardians had signed an assent form (Appendix 2) and a consent form (Appendix 1).
- Subjects had to reside at the various homes.

### **3.3.5 Exclusion criteria**

- Subjects on enuresis related treatments were excluded.
- Subjects with relevant anatomical abnormalities; neurological or otherwise were excluded.
- Subjects presenting with any other illness that could clinically contribute to their enuretic condition were excluded.
- Subjects with lactose intolerance were excluded.

## **3.4 Experiment design and procedure**

### **3.4.1 Obtaining the sample**

Children's homes were contacted and asked whether they were interested in participating in the research study. They were then asked to provide an indication of the number of children who bedwet and the number of incidences per child. Following this a meeting with the guardians and caregivers was set up. The objectives and methods including homoeopathic consultation, treatment and physical examination were explained in detail. Once they had understood and agreed to the trial the guardians were required to sign the consent form for each potential participant (Appendix 1), followed by each child signing an assent form (Appendix 2).

### **3.4.2 Interview and consultation**

At the beginning of the initial interview the aims and objectives, treatment, physical examination procedures and trial design was explained to each subject. The subjects who agreed to participate were then asked to sign an assent form (Appendix 2). The assent form is the equivalent of a consent form but worded in such a way as to make it child-friendly. This interview was followed by a consultation, which included a physical examination (Appendix 5) and a medical case history aimed at establishing any known causes of nocturnal enuresis in addition to a homoeopathic enquiry (Appendix 4). The purpose of this consultation was to ensure that participants met the inclusion criteria, as well as to obtain the necessary information to establish the similimum. In most instances the caregivers were interviewed in order to obtain additional information. The subjects were screened and examined for (Appendices 4 and 5):

- infrequent or day time wetting,
- recurrent urinary tract infections
- anatomical and neurological abnormalities that might complicate or result in nocturnal enuresis
- systemic or metabolic causes e.g. hyperglycaemia
- worm infection
- urinary tract infections and hyperglycouria (urine dipstick)

### **3.4.3 The Process of Randomisation**

After the establishment of the sample group the 66 subjects were divided into three sub-groups / projects (homoeopathic similimum, homoeopathic complex and *Ilex paraguayensis*); in addition each sub-group was randomly subdivided into a placebo and treatment group. The various subjects were allocated into three age categories (5-8, 9-12, 13-18) as well as divided along gender lines. The purpose of this was to ensure age and gender uniformity amongst all three sub-groups / projects. After this the supervisor randomly selected a placebo group from the above three sub-groups / projects. This placebo group contained a similar age and gender distribution as the treatment groups. The randomisation was carried out in order to ensure the double blind nature of the trial. Each researcher knew the identities of their group members, but were unaware as to who was part of the placebo group. Similarly the participants of the trial were aware of the presence of a placebo group, but were unaware of its members.

#### **3.4.4 Identifying the similimum**

Upon completion of the initial interview and consultation each case was individually analysed for the homoeopathic similimum. A treatment protocol was subsequently created for each child and was ratified by the clinical supervisors at the Durban Institute of Technology homoeopathic day clinic. The final scripts were then forwarded to the dispensing staff who held the randomisation list.

#### **3.4.5 Medicine preparation**

An appointed member at the Durban Institute of Technology homeopathic clinic dispensed the remedies. The homoeopathic remedies were prepared in granule form, which were then dispensed into lactose powders. The placebo group received lactose powders containing unmedicated granules whereas the treatment group received lactose powders containing medicated granules. Each child received fourteen numbered powders in two packs of seven. The appearance, presentation and administration of powders were identical for both placebo and treatment groups, as well as for all three research projects.

#### **3.4.6 The trial**

After the interview and homoeopathic consultation there was a waiting period of 6 weeks before the trial began. It was hoped that this period would reduce the possible placebo effect of the initial contact with the children. At the beginning of the trial, subjects were observed for two weeks to determine the baseline number of wet nights per week. To facilitate this process each subject was provided with a weekly diary (Appendix 6), that was marked with either a "W" or a "D" (wet or dry) each morning by the resident caregiver. The diary was collected at the end of each week by the researcher, and a new one provided. This allowed the caregivers to communicate any problems with diary keeping to the researchers.



The baseline period was followed by a two-week treatment period. At the beginning of each week each subject received powders numbered 1 to 7 along with a one-week diary. The caregivers administered these powders before bed each night. At the end of each week diaries were collected and the following week's remedies and diaries provided. Again this provided an opportunity for caregivers to communicate any difficulties with diaries or medication to the researchers.

Following the treatment period of two weeks the subjects were observed for a period of four weeks, with diaries, but without further treatment. This period was used to statistically evaluate the impact of the treatment i.e. was there any change in frequency of bed wetting in comparison to the baseline period (weeks one and two). There was a final consultation at the end of these four weeks. Children who showed improvement were referred to the homeopathic day clinic and placebo members were identified and offered free treatment. All examinations, special tests and treatment administered to the subjects during this study were free of charge.

### **3.5 Double blind**

This was a placebo controlled, double blind and randomised study. Enuresis is not a life threatening condition, nor were the children in the homes currently being treated. In addition the children participating in this study were informed of the possibility that they may receive placebo before the trial began. Bearing this in mind the researchers considered it ethically acceptable to use a

placebo group as a measure against which treatment could be compared. At the completion of the study those that received placebo were informed and offered treatment free of charge.

The 66 subjects involved were randomly divided into three groups of 22 subjects each. All groups underwent the same consultation and examination procedures and received their treatment in the same form and at the same time intervals. Each subject in the treatment group received a homoeopathic similimum, whilst those in the placebo group received placebo treatment. The researchers knew the subjects in their group but were not aware as to who was receiving treatment or placebo. The powders were administered before bed each night. The treatment and placebo powders were identical in appearance, taste and smell. The use of a collective placebo was motivated on the grounds that all interviews, consultations and posology were uniform amongst the three projects. In addition the trials were simultaneously run and comprised children from the same homes.

### **3.6 Measurements**

At the end of each week the data for each subject was plotted onto a bar graph to indicate the progress (or lack thereof) made during the study. At the completion of the study period, the data as an entirety was collated, analysed and interpreted by means of statistical methods. The final analysis was made using a collective placebo group of 16 subjects derived from the three research projects.

Data was extracted from the following sources:

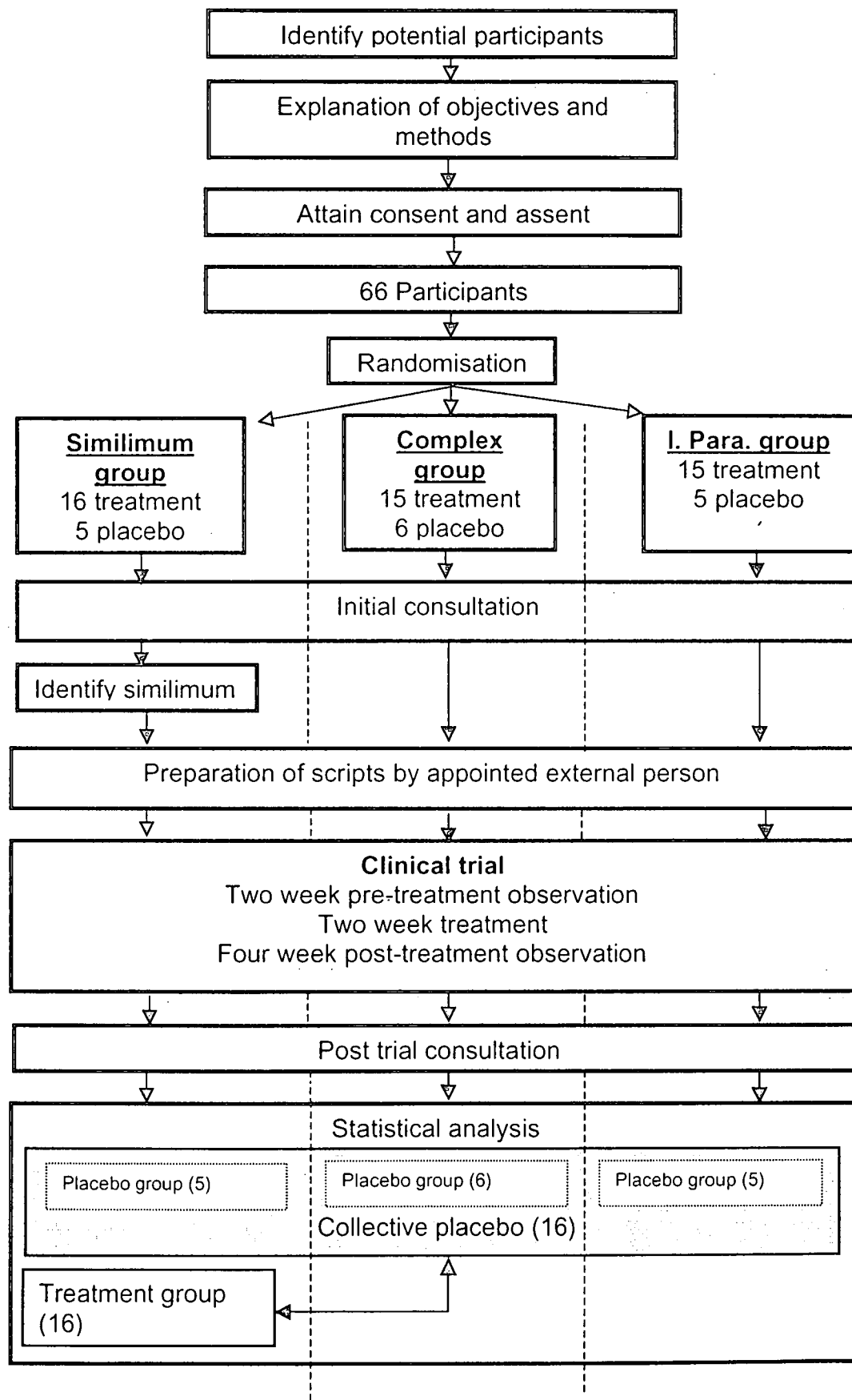
- Past medical records
- Case history record
- Physical examination records
- Diaries indicating wet nights per week

### **3.7 Statistical Treatment of Data**

The body of the data obtained was analysed using three procedures as discussed in Chapter 1. These employed the following statistical tests:

- The Wilcoxon's Signed Rank test to compare the groups within themselves (intra-group comparisons). This test was used in procedures one and two and analysed the treatment and placebo group independently of one another. Different time periods were compared within the study (Figures 8 and 9) to determine the statistical significance of the results for each group (Tables 5-15).
- The Mann Whitney U test to compare treatment and placebo groups (inter-group comparisons). This test was used in procedure three and compared various time periods in the study (Figure 10). It sought to determine the statistical relevance of the results by comparing the two groups (Table 16).
- Summary statistics were used to present demographic data. The data presented includes gender distribution, age distributions, and incidences at the different homes (Figures 3-5 and Tables 1-2).

**Figure1 Summary of research design**



## CHAPTER 4

### RESULTS

#### 4.1 Introduction

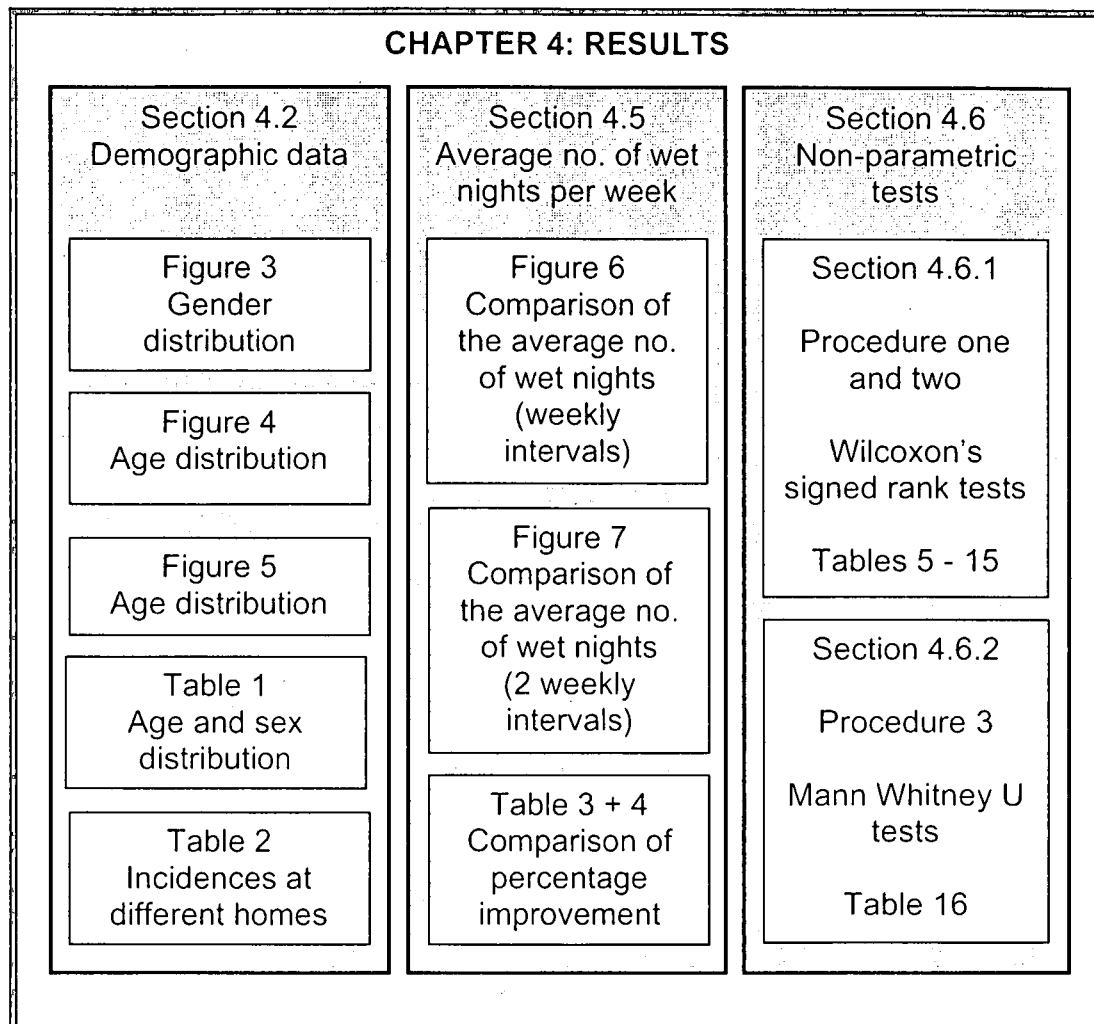
This chapter covers the results from the trial. It presents demographic and statistical data. In addition it provides a list of the remedies used.

The first set of data presents demographic data obtained from the patients' files and records at the children's homes (section 4.4).

The second set of data presents the average / median number of wet nights per week obtained for both the treatment and placebo groups (section 4.5).

The third set of results presents statistically analysed data (section 4.6). It seeks to determine the efficacy of each treatment regime (similimum and placebo) by evaluating intra-treatment and inter-treatment data. Intra-treatment data refers to comparisons made within a group, with both treatment and placebo groups being analysed independently (Wilcoxon's signed rank tests - procedures one and two). Inter-treatment data refers to comparisons made between both groups i.e. the placebo and treatment groups are compared using the same time intervals (Mann Whitney U tests - procedure three). The null and alternative hypotheses were either accepted or rejected based on the results.

**Figure 2 Summary of results**



## 4.2 Abbreviations

P = two tailed probability of equalling or exceeding  $Z/2$

ns = no significant difference in the medians

s = significant difference in the medians

Plcb = Placebo group

Trt = Treatment group

If  $P \leq 0.05$  = significant difference (5% level of significance) = s

If  $P \geq 0.05$  = no significant difference (5% level of significance) = ns

Ho = Null hypothesis

Ha = Alternative hypothesis

Wk = week

Bsl = Base line = The average number of wet nights in weeks one and two

P1 = Period 1 = The average number of wet nights in weeks three and four

P2 = Period 2 = The average number of wet nights in weeks five and six

P3 = Period 3 = The average number of wet nights in weeks seven and eight

P4 = Period 4 = The average number of wet nights in weeks five to eight

P5 = Period 5 = The average number of wet nights in weeks three to eight

#### **4.3 Criteria governing admissibility of the data**

- Only data from compliant subjects was admitted and analysed (subjects had to have both a completed consent and assent form as well as verbal confirmation from the caregivers that the medicine was administered).
- The only source of data was the enuretic diaries and case histories i.e. gender, age and wet nights per week.
- The data was only admissible if the diaries were correctly completed.

#### 4.4 Demographic data of the sample

Figure 3 Gender distribution of subjects

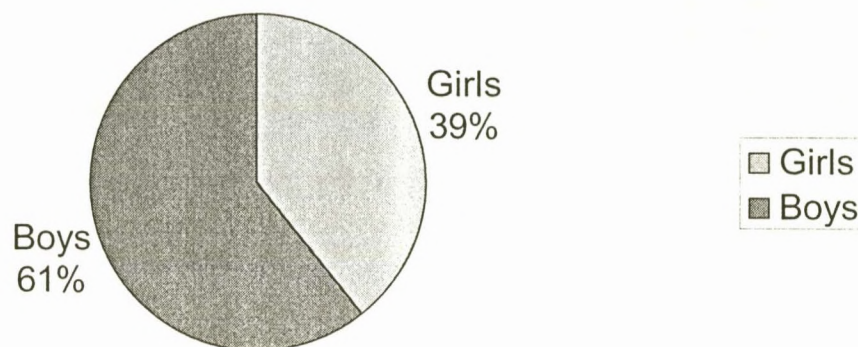
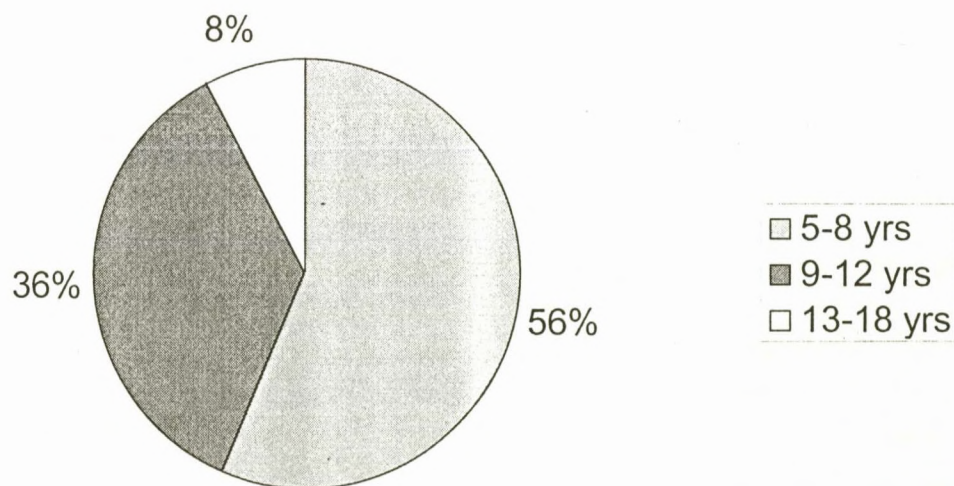
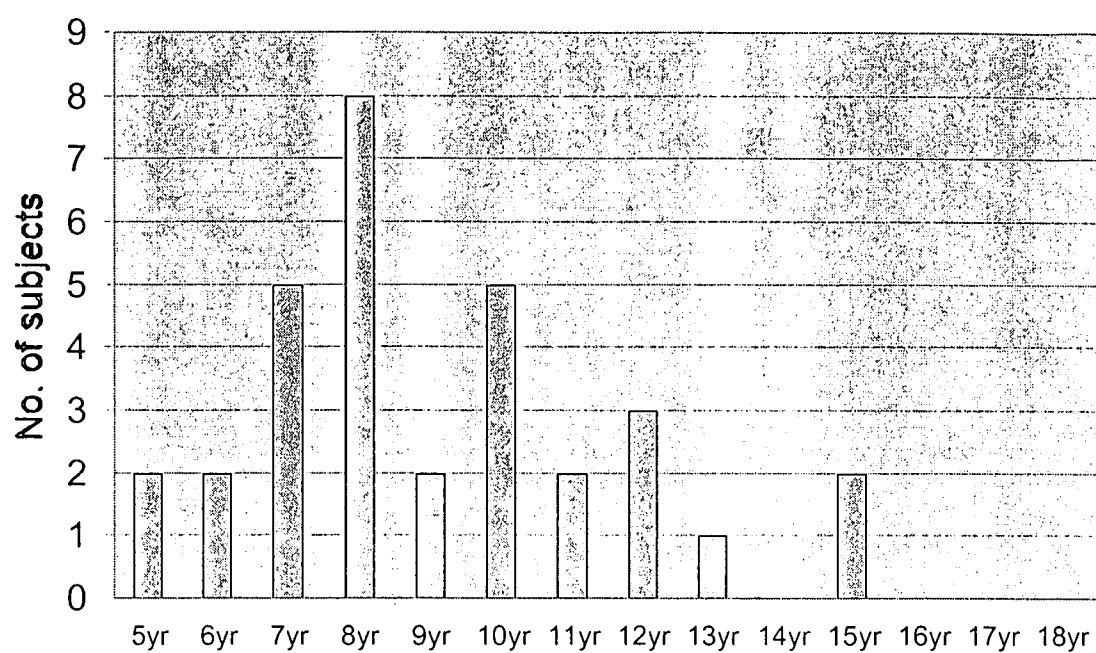


Figure 4 Age distribution (5-8 yrs, 9-12 yrs, 13-18 yrs)





**Figure 5 Age distribution**



**Table 1 Age and sex distribution of subjects**

	Total number	Average age	No. of boys	Average age	No. of girls	Average age
Treatment	16	9.43	11	9	5	9.25
Placebo	16	9.25	9	9.55	7	8.42

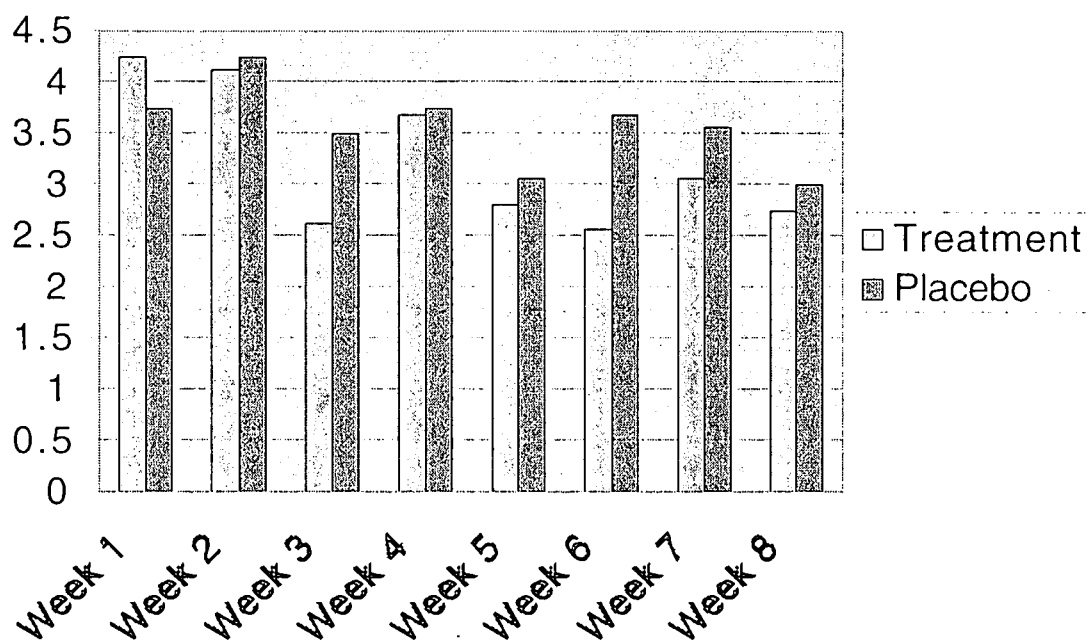
**Table 2 Incidences at different homes**

Homes	Population between 5-18 yrs	Number of bedwetters	Percentage incidence
1	72	17	23.6%
2	75	9	12%
3	82	8	10.25%
4	39	6	15.3%
5	68	4	5.8%
6	70	4	5.7%
7	31	6	19.3%
8	15	4	26.6%
9	120	6	5%
Total	572	64	11.1%

#### 4.5 Comparisons based on the average / median number of wet nights per week and percentage improvement

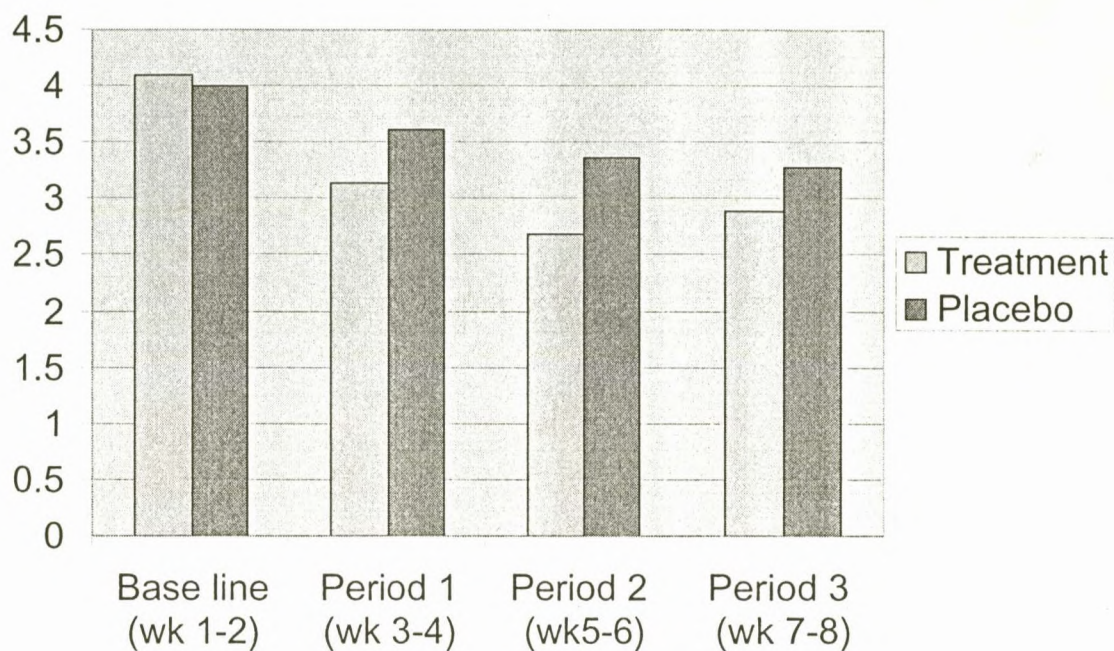
##### 4.5.1 Comparisons of the average / median number of wet nights per week

**Figure 6** Comparison of the average wet nights per week in the placebo and treatment group



The above figure presents a fluctuating picture representing the natural variation in occurrence. The placebo group shows a number of variations with the results being statistically significant in weeks five and eight. The treatment group shows consistently fewer incidences, which are statistically significant except for week four. The sudden spike in week four in the treatment group is interesting and could represent a slight homoeopathic aggravation.

**Figure 7 Comparison of average wet nights in the placebo and treatment group at two weekly intervals**



The above figure based on two weekly averages allows for clearer trends to be established. The number of incidences in the initial observation period is for all intensive purposes the same for the placebo and treatment group.

Thereafter the number of incidences between the groups becomes noticeably different (but statistically not), with the treatment group showing fewer incidences. Although both groups show improvement, the treatment group shows fewer incidences throughout. The placebo group shows a gradual improvement, which although not statistically significant is observable. The treatment group shows a greater level of improvement, which is statistically significant in period one.

#### 4.5.2 Comparisons of the improvement between the placebo and treatment group based on percentage differences

**Table 3** Comparison of the improvement in the placebo and treatment group based on the percentage difference between the baseline period (weeks 1-2) and period 4 (weeks 5-8)

	Neg. results	0-24% impr	25-50% impr	50-74% impr	75-100% impr	Sample size
Plcb	5	3	5	3 *	0	16
Trt	4	3	3	6 *	0	16

The above data reflects that there was a 37.5% (6 out of 16) success rate in the treatment group and a 18.75% (3 out of 16) success rate in the placebo group. For the purpose of this study the success rate was defined as 50% reduction in bedwetting.

**Table 4** Comparison of the improvement in the placebo and treatment group based on the percentage difference between the baseline period (weeks1 -2) and the period 5 (weeks 3-8)

	Neg. results	0-24% impr	25-49% impr	50-74% impr	75-100% impr	Sample size
Plcb	4	6	4	2 *	0	16
Trt	5	3	4	4 *	0	16

The above table shows that the success rate declined for the comparison of the baseline and period 5. The success rate for the placebo group is 12.5% and 25% for the treatment group.

#### 4.6 The analysed data using non-parametric tests

This section presents the non-parametric analysis of the data obtained from the enuresis diaries. It employed the SPSS computer package to analyse the data using the Wilcoxon's Signed Rank test to compare the groups within themselves (procedures one and two - intra-group analysis) as well as the Mann Whitney U test to compare treatment and placebo groups (procedure three - inter-group analysis).

#### **4.6.1 Procedures one and two (intra-group comparisons using Wilcoxon's signed rank tests)**

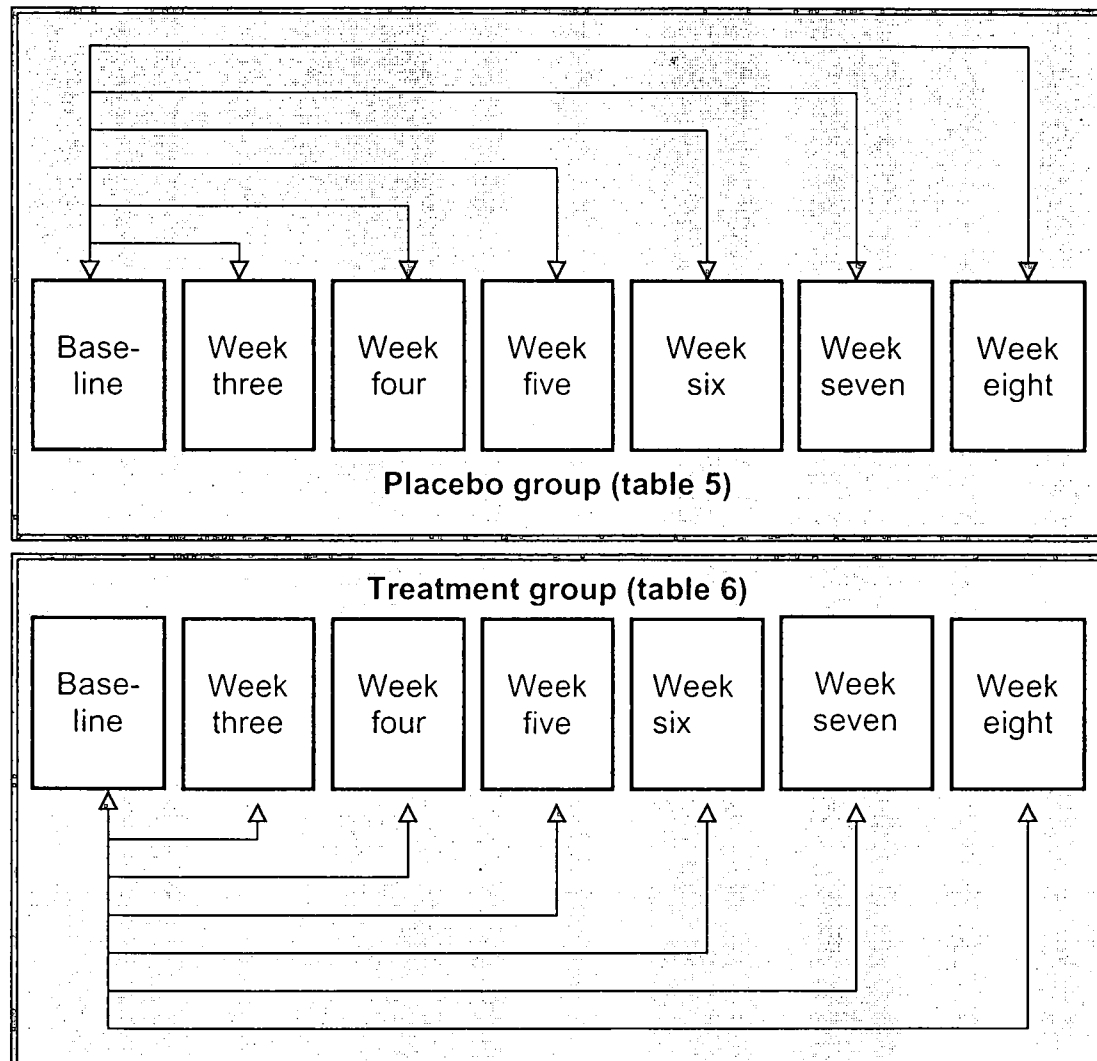
Ho: The null hypothesis states that there is no statistical difference with regards to the average number of wet nights on intra-group analysis. This indicates that there was no statistically significant improvement in the condition.

Ha: The alternative hypothesis state that there is a statistical difference with regard to the number of wet nights on intra-group analysis. This indicates that there was a statistically significant improvement in the condition due to treatment.

All tests were carried out using the Wilcoxon's Signed Rank test at 95% degree of confidence. Thus a 5% level of significance was employed where the alternative hypothesis was accepted if  $p \leq 0.05$ .

**Figure 8 Summary of Wilcoxon's signed rank tests for treatment and placebo group (procedures one and two - intra-group analysis)**

This diagram demonstrates the comparisons used for tables 5 and 6.



**Table 5 A sample analysis of the placebo group's diaries comparing the average number of wet nights of the baseline period to each week of the study using Wilcoxon's Signed Rank test**



Placebo	bsl-wk3	bsl-wk4	bsl-wk5	bsl-wk6	bsl-wk7	bsl-wk8
p value	0.586	0.802	0.044	0.569	0.242	0.029
	ns	ns	s	ns	ns	s

The null hypotheses were accepted for weeks three, four, six and seven, because at a 5% level of significance there was no significant difference between these weeks and the baseline period indicating no significant improvement in the subjects' conditions during these weeks. However for weeks five and eight the null hypothesis was rejected and the alternative hypothesis was accepted, because at a 5% level of significance there was a significant difference between these weeks and the baseline period indicating an improvement in the subjects' condition.

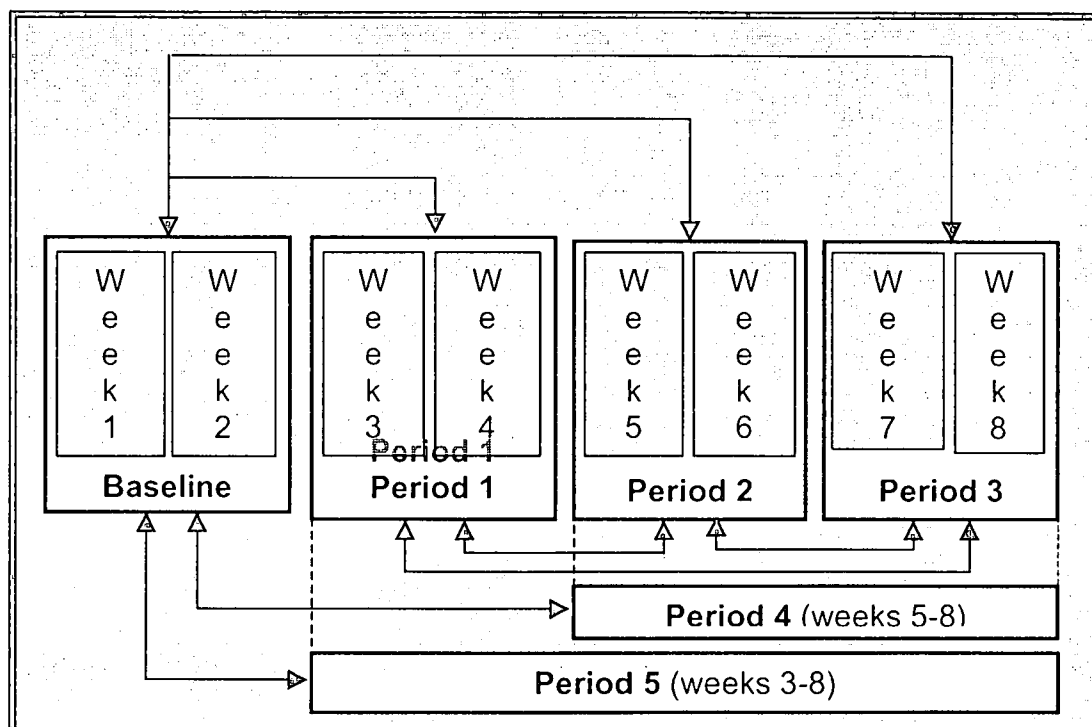
**Table 6 A sample analysis of the treatment group's diaries, comparing the average number of wet nights of the baseline period to each week in the study using Wilcoxon's Signed Rank test**

Trt	bsl-wk3	bsl-wk4	bsl-wk5	bsl-wk6	bsl-wk7	bsl-wk8
p value	0.026	0.461	0.016	0.004	0.032	0.029
	s	ns	s	s	s	s

The null hypothesis was accepted for week four, because at a 5% level of significance there was no significant difference between this week and the baseline period. The null hypothesis was rejected and the alternative

hypothesis accepted for weeks three, five, six, seven and eight, because at a 5% level of significance there was a significant difference in the results indicating an improvement of the subject's condition.

**Figure 9** Summary of Wilcoxon's signed rank tests for placebo and treatment groups (procedures one and two- intra-group analysis)



**Table 7** A sample analysis of the placebo and treatment group comparing the baseline (weeks one and two) and period 1 (weeks three and four) within each group

Baseline - period 1	p value
Placebo	0.657 ns
Treatment	0.077 ns

The null hypothesis was accepted as it was concluded that at a 5% level of significance there was no statistically significant improvement between the baseline and period 1 in either of the groups.

**Table 8 A sample analysis of the placebo and treatment group comparing the baseline (weeks one and two) and period 2 (weeks five and six) within each group**

Baseline - period 2	p value
Placebo	0.151 ns
Treatment	0.005 s

The null hypothesis was accepted for the placebo group because at a 5% level of significance there was no statistically significant improvement in the subjects' condition. The null hypothesis was however rejected in favour of the alternative hypothesis for the treatment group because at a 5% level of significance there was a statistical improvement in this comparison.

**Table 9 A sample analysis of the placebo and treatment group comparing the baseline (weeks one and two) and period 3 (weeks seven and eight) within each group**

baseline - period 3	p value
placebo	0.94 ns
treatment	0.180 ns

The null hypothesis was accepted as it was concluded that at a 5% level of significance there was no statistically significant improvement in either of the groups in this comparison.

**Table 10** A sample analysis of the placebo and treatment group comparing the baseline (weeks one and two) and period 4 (weeks five to eight) within each group

baseline - period 4	p
placebo	0.097 ns
treatment	0.008 s

The null hypothesis was accepted for the placebo group because at a 5% level of significance there was no statistically significant improvement in the subjects' condition. The null hypothesis was however rejected in favour of the alternative hypothesis because at a 5% level of significance there was a statistically significant improvement in the treatment group.

**Table 11** A sample analysis of the placebo and treatment group comparing the baseline (weeks one and two) and period 5 (weeks three to eight) within each group

baseline - period 5	p value
placebo	0.139 ns
treatment	0.017 s

The null hypothesis was accepted for the placebo group because at a 5% level of significance there was no statistically significant improvement in the subjects' condition. The null hypothesis was however rejected in favour of the alternative hypothesis because at a 5% level of significance there was a statistically significant improvement in the treatment group.

**Table 12** A sample analysis of the placebo and treatment group comparing period 1 (weeks three and four) and period 2 (weeks five and six) within each group

period 1 - period 2	p value
placebo	0.663 ns
treatment	0.180 ns

The null hypothesis was accepted as it was concluded that at a 5% level of significance there was no statistically significant improvement in either of the groups in this comparison.

**Table 13** A sample analysis of the placebo and treatment group comparing period 1 (weeks three and four) and period 3 (weeks seven and eight) within each group

period 1 - period 3	p value
placebo	0.246 ns
treatment	0.475 ns

The null hypothesis was accepted as it was concluded that at a 5% level of significance there was no statistically significant improvement in either of the groups in this comparison.

**Table 14 A sample analysis of the placebo and treatment group comparing period 2 (weeks five and six) and period 3 (weeks seven and eight) within each group**

period 2 - period 3	p value
placebo	0.153 ns
treatment	0.404 ns

The null hypothesis was accepted as it was concluded that at a 5% level of significance there was no statistically significant improvement in either of the groups in this comparison.

**Table 15 A sample analysis of the placebo and treatment group comparing period 4 (weeks five to eight) and period 5 (weeks three to eight) within each group**

Period 4 - period 5	p value
placebo	0.139 ns
treatment	0.017 s

The null hypothesis was accepted for the placebo group because at a 5% level of significance there was no statistically significant improvement in the subjects' condition. The null hypothesis was however rejected in favour of the alternative hypothesis because at a 5% level of significance there was a statistically significant improvement in the treatment group.

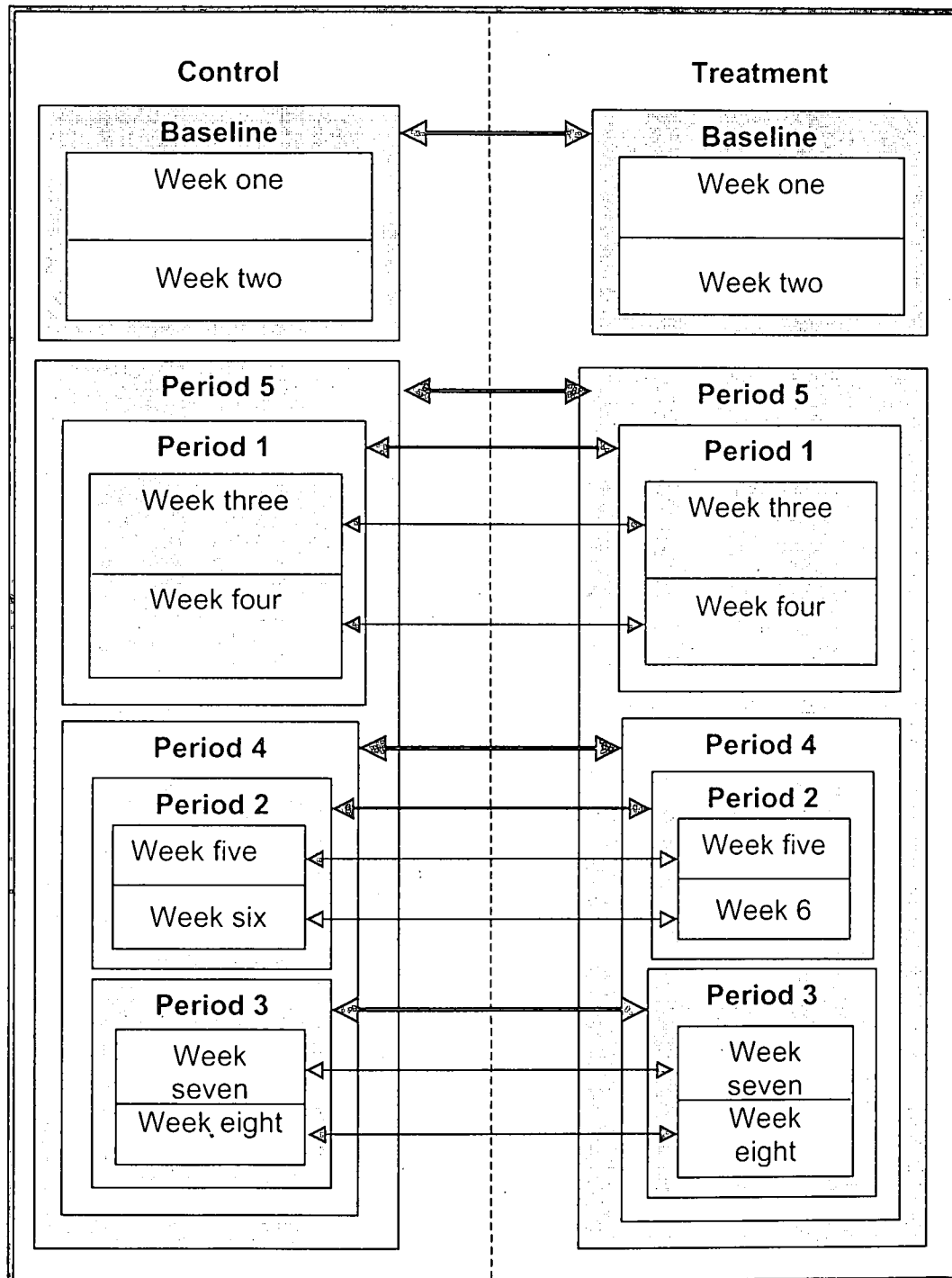
#### 4.6.2 Procedure three (inter-group comparisons using the Mann Whitney U tests)

Ho: The null hypothesis states that there is no statistical difference with regards to the number of wet nights in the placebo and treatment groups.

Ha: The alternative hypothesis states that there is a statistical difference with regards to the number of wet nights in the placebo and treatment groups.

All tests were carried out using Mann-Whitney U test at a 95% degree of confidence. Thus a 5% level of significance was employed where the alternative hypothesis was accepted if  $p \leq 0.05$ .

**Figure 10 Summary of Mann Whitney U tests**





**Table 16** A statistical comparison between the placebo and treatment groups for different periods using the Mann-Whitney U test

	p value
baseline	0.569 ns
week no. 3	0.260 ns
week no. 4	0.985 ns
week no. 5	0.818 ns
week no. 6	0.102 ns
week no. 7	0.644 ns
week no. 8	0.670 ns
period 1	0.438 ns
period 2	0.325 ns
period 3	0.505 ns
period 4	0.406 ns
period 5	0.594 ns

The null hypothesis was accepted because at a 5% level of significance there is no statistically significant difference between the placebo and treatment group for the mentioned comparisons. This is significant particularly for the baseline period, a statistically significant difference would indicate that the baseline sample is an inappropriate measure against which other results could be compared.

#### 4.7 Remedies used in the study

The following table presents a list of the remedies used for different children. The remedies were arrived at through careful case analysis and subsequent repeterisation of the characteristic totality of symptoms using the computerised Mac Repetory, version 5.6 by Van Zandvoort (2000).

**Table 17 Remedies used in the study**

Case number	Similimum
1	Tuberculinum bovinum
2	Calcarea carbonica
3	Sulphur
4	Tuberculinum bovinum
5	Sulphur
6	Pulsatilla pratensis
7	Lac caninum
8	Thuja occidentalis
9	Pulsatilla pratensis
10	Sulphur
11	Stramonium datura
12	Medorrhinum
13	Tuberculinum bovinum
14	Pulsatilla pratensis

15	Carcinosinum
16	Sulphur

See Appendix 7 for repertory sheets, rubrics and scripts.

## CHAPTER 5

### DISCUSSION

There have been a number of treatment modalities introduced for functional nocturnal enuresis. As previously discussed in the literature review these are divided into pharmacological and non-pharmacological approaches. The most popular drugs are Imipramine hydrochloride (Tofranil ®) and Desmopressin (DDAVP). The success rate for Tofranil ® ranges from 25 to 50% with a 30% relapse rate (Ullom-Minnich, 1996: 2259). Side effects are common and range from insomnia to personality changes and nervousness as well as the danger of overdose (Cendron, 1999:9). Desmopressin is fast acting and useful in cases of parental intolerance or to avoid embarrassment if a child is sleeping away from home. It has a success rate of 40%, but its action ceases on withdrawal. The most significant non-pharmacological approach appears to be dry bed training (85 to 100% success rate), which includes night waking, cleanliness training, positive practice and the alarm system.

Based on a rational definition that 50% reduction in bedwetting defines success, the results of this study indicate a clinically significant improvement. The placebo group showed a 12.5 - 18.75% improvement whereas the treatment group showed a 25 - 37.5% improvement. This variation in success rate is dependent on whether period 1 (the treatment period) is incorporated into the results or not, with the lower figure indicating inclusion (see tables 3 and 4). It is the researcher's opinion that the lower percentage be accepted as

the action of the similimum as well as the placebo can be immediate. It is however well accepted in homoeopathic literature that an aggravation of the presenting condition can occur after the administration of the similimum. An aggravation may be severe or sub-clinical and is usually followed by an amelioration of the presenting complaint. This may explain the increase in incidences of bedwetting in week four in the treatment group and thus may suggest that the higher figure of success be assumed i.e. that weeks 5-8 are used as a measure of improvement vs. weeks 3-8.

The average baseline frequency of bedwetting (weeks 1-2) was 3.87 incidences for the placebo group and 4.18 incidences for the treatment group. The difference between the groups is statistically insignificant ( $p=0.569$ ), this is important as a statistically significant difference would indicate that the baseline is an inappropriate measure of comparison. There is however a greater degree of variance in the baseline period if one views weeks one and two independently. The average number of incidences for weeks one and two was 3.75 and 4.25 for the placebo group, and 4.25 and 4.12 for the treatment group. Once again an intra and inter-group comparison of these figure yields a statistically insignificant result (see table 15).

The variance in the number of incidences per week in the placebo group is notable, as graphically demonstrated by Figure 4. There is no apparent trend or much statistical significance in comparing weeks 3-8 to the base line period. The only statistically significant difference to the baseline period occurred in week 5 ( $p=0.44$ ) and week 8 ( $p=0.029$ ). The p value in week 5 is

however close to being considered insignificant i.e.  $p=0.05$ . The statistical analysis (table 5) using Wilcoxon's Signed Rank test suggests that little or no improvement can be demonstrated in the placebo group despite the 12.5 - 18.75% success rate noted earlier.

This is seen in contrast to the treatment group where the intra-group analysis (table 6) is statistically significant apart from week 4 ( $p=0.461$ ). The possible reasons for this has been discussed above. This improvement is graphically demonstrated in figures 4 and 5, and is noteworthy.

The inter-group comparisons (comparisons between the placebo and treatment groups) using the Mann-Whitney U test are all statistically insignificant (table 15). The use of this test in addition to Wilcoxon's Signed Rank test helps to validate the degree of statistical improvement. If both tests yield significant improvement the results are very significant i.e. there is an improvement within a group as well as an improvement when compared to the equivalent periods in the other group. This is however not the case, the results although significant for the signed rank test, are insignificant for the U test and are thus relatively graded.

Despite the lack of statistically verifiable improvement the action of the placebo on the placebo group is graphically demonstrated in figure 5. Similarly the greater improvement in the treatment group can also be seen. The climb in number of incidences in period 2 in the treatment group suggests that this would have been an appropriate time for a follow up consultation and re-

medication. In addition this figure demonstrates that the number of incidences in the treatment group was consistently lower than the placebo group apart from the baseline period where they are similar.

On examination, the results for intra-group data for both the summary period (weeks 3-8) and period 3 (weeks 5-8) are statistically significant for the treatment group but insignificant for the placebo group (table 13 and 14). The p values for period 3 and the summary for the placebo group are 0.097 and 0.139 suggesting statistical insignificance i.e. no improvement. In contrast the above figures for the treatment group are statistically significant and suggest a noteworthy improvement in this group ( $p=0.08$  +  $p=0.017$ ).

The demographic data although representing a small sample supports various texts. Firstly more boys are affected than girls as demonstrated by the sample breakdown (69% boys and 31% girls). Secondly, a higher prevalence is noted in younger children. In this study 56% of the children were between 5-8 years, 36% were between 9 and 12 years and only 8% were between 13 and 18 years. This supports the notion that bedwetting has a spontaneous resolution rate of 15% per annum.

More confusing however is the prevalence at various homes. Of the nine homes sampled, the prevalence varies between 23.6% and 5%, with an average of 11.1%. This variance may partially be explained by the different age groupings at the various homes, with some homes catering more for older children. This however does not fully explain the data. It is the researcher's

opinion that a more relevant reason would be the different attitudes and levels of care at the various homes. Some of these factors affecting this include the ratio of children to care giver, the total population at the home, available resources, age distributions at different homes and the degree of training and experience of the care-givers.

The above analysis presents the results of the study in a rational way. Such an approach is useful on a number of levels including the current need for homoeopathy to justify itself rationally. It however leaves a number of questions unanswered and fields of enquiry unexplored. One of the largest problems in clinical trials involving homoeopathy is that the similimum varies from subject to subject. Thus rather than testing a given drug one is evaluating an approach or a modality. The efficacy of this is affected by a number of factors and thus results will automatically vary from trial to trial.

Implicit to the identification of the similimum is the homoeopath. Different practitioners vary in age, gender, expertise, experience and approach. Thus the results of any trial involving the similimum are as much an evaluation of the practitioner as it is the modality. Although the researcher received clinical supervision, it must be noted that he is relatively inexperienced.

A second factor is the information that one receives from the patient. Although much of the information is objective e.g. sleep position, odour of urine, medical history etc., the most important information is subjective or qualitative. This is especially significant in the arena of children's homes where many of



the children have been traumatised, abused or abandoned. The ability to establish this history, the child's relation to it or even the personality of the child is difficult, and is often dependent on the rapport that the practitioner has with the patient as well as their interviewing skills. In addition to this many of the children have scant family or medical history and thus many areas of enquiry are sealed e.g. developmental milestones, vaccination history etc.

Another significant stumbling block was the information received from the caregivers. Although many of the caregivers could adequately describe the personality of the children and how they interacted, others couldn't. This is more a statement of the conditions at the homes where there are often twelve or more children to a caregiver rather than a critique of their skills. From the above discussion it can be seen that homoeopathy is context specific and is reliant on the skills of the practitioner, their relationship with the patient as well as the interpretation of the available information. This is seen in contrast to the allopathic approach, which is diagnosis driven and less context specific.

Another area of debate is the expectation of cure or the action of the similimum. The concept of individualisation is inherent to homoeopathy and runs through every level from the patient, to the practitioner, to the remedy and ultimately to the response to the remedy. Considering the history of the many of the children, it seems unreasonable to stimulate cure with a single prescription. Furthermore what is cure? Although from the perspective of this clinical trial it is the absence of bedwetting, from a homoeopathic level it is an improvement on every level. It is homoeopathically well recognised that if a

given trauma is very deep, improvement will often be seen on a mental or general level before changes are seen in the actual complaint. In addition these changes are not statistically measurable. This points to a need for a more qualitative approach to assessing improvement especially in the context of children's homes. Secondly it suggests that treatment needs to be carried out over a longer period of time. Given the results from a single treatment it is quite feasible that even greater improvement could be seen with a number of follow up visits and scripts. In addition those children that did not respond to their initial script could be offered another remedy.

An inherent problem in clinical studies involving homoeopathic similimum is the paradigm in which the results are analysed. This study is no exception to this in that a single variable is used as a measure of success. This typifies the allopathic approach, where diagnosis and treatment are specific to a single complaint or health problem. This approach is diametrically opposed to a homoeopathic perspective where the patient is viewed in totality. Essential to the homoeopathic analysis of a case is the identification of the characteristic totality of symptoms as is found on the mental, emotional and physical planes. This totality is necessary for the identification of the similimum, as well as for evaluating the patient's response to the similimum. Numerous authors (Vithoulkas, Ghegas, De Scheeper etc) agree that the follow up consultation should include a careful review of all the patient's symptoms with special attention being given to the characteristic totality of the patient. On such an overview the practitioner may find that there is improvement on some planes but not on others. Thus the patient may be improved on a mental or emotional

level without significant change to the main complaint. Regardless of this it is still an indication of improvement as well as the action of the similimum. This is particularly true for the children involved in this study, with many of them having severe emotional symptomatology as an accompaniment to their enuretic problem. From the homoeopathic paradigm improvement of these problems is more significant than an improvement of their nocturnal enuresis. In addition an improvement on a mental, emotional or general level would generally be accepted to be pre-emptive of an improvement of the nocturnal enuresis.

Despite the above arguments the trial has been shown to have statistically relevant results. This is promising if one regards the full context of the problem as well as the inherent difficulties in demonstrating results with a single homoeopathic script.

## CHAPTER 6

### CONCLUSION

This double blind, placebo controlled and randomised study has shown promising results in the treatment of nocturnal enuresis. The analysis of the data shows a statistically significant improvement in the treatment group supporting the efficacy of homoeopathic similimum in the treatment of this condition. This is viewed in the light of the largely insignificant results obtained in the control group. The success rate of between 25 and 37.5% for a single treatment is suggestive of the beneficial outcomes that longer-term treatment might offer. The use of the homoeopathic similimum is ideal in the treatment of children in that it offers a safe and side effect free treatment to a range of conditions apart from nocturnal enuresis. In addition it is a modality which can effectively target mental and emotional crises that are prevalent at children's homes, and which often accompany other conditions. This is due to the ability of the homoeopathic approach to view and treat each patient as a totality rather than treating each area of concern separately.

Completion of this study has brought to light a number of shortfalls.

Suggestions for improvement are listed below.

- Increase the baseline period to a month or three weeks.
- Ensure that the study is run over a longer period of time with a minimum of two follow-up scripts.
- Use a combined qualitative / quantitative approach in evaluating results.

- Increase the sample size.
- Use a non-pharmacological approach against which outcomes are measured rather than placebo.
- Run the trial in other contexts i.e. not in children's homes.

## CHAPTER 7

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## CHAPTER 8 APPENDICES

### Appendix 1: Parent / Guardian Consent Form

Title of research project: A double blind study to determine the efficacy of a homoeopathic complex (Cantharis vesicatoris 12ch, Equisitum hyemnale 12ch, Sarsparilla 12ch, Staphisagria 12ch, Uva ursa 12ch), Ilex paraguayensis 6x and the homoeopathic similimum in the treatment of nocturnal enuresis in children between five and eighteen years, residing in children's homes.

Name of supervisor: Dr C Hall

Name of research students: M Bloch, H Lockyear and P Reilly

(Please circle the appropriate answer)

Have you read the information form? Yes/No

Have you had the opportunity to discuss this study with the above research students? Yes/No

Have you had the opportunity to ask questions regard this study? Yes/No

Have you received satisfactory answers to your questions? Yes/No

Do you understand that participants are free to withdraw from the study at any time? Yes/No

Do you understand the nature of this research project and its structure? Yes/No

Do you agree to allow your child or children under your care to participate in this study? Yes/No

Do you agree to allow the researchers access to relevant medical records? Yes/No

(If you have answered no to any of the above questions please consult the researchers.)

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

.....  
Signature parent/ guardian

.....  
Witness signature

Date.....

## Appendix 2: Minor assent form

My name is.....

- I wish to take part in your research project.
- The project has been carefully explained to me.
- I am not being forced to take part.
- I understand that I can decide not to take part at any time.

.....  
Signature

Date.....

---

Igama lami lingu.....

- Nginaso isifiso sokubamba iqhaza ocwaningweni lakho.
- Lolu cwaningo luchaziwe kabanzi kimina.
- Angiphoqelelwanga ukubamba iqhaza.
- Ngiyazi ukuthi ngingawushintsha noma inini umqondo mayelana nokubamba iqhaza.

.....  
Sayina

Usuku.....

### **Appendix 3: Patient information sheet**

The purpose of this study is to determine the efficacy of a homoeopathic complex, Ilex paraguayensis and the homoeopathic similimum in the treatment of nocturnal enuresis.

Homoeopathy: According to the World Health Organisation homoeopathy is the second most widely used form of therapy worldwide. Homoeopathic remedies produce no side effects and thus bring about cure in a gentle manner and are safe for use in children. Homoeopathy was founded by S. Hahneman two hundred years ago and is based on the law of similars. This implies that a homoeopathic remedy will cure a disease state similar to that which it can cause when administered to a healthy person.

Homoeopathic complex: A homoeopathic complex comprises a number of remedies that are known to have an effect on a particular condition. For the purposes of this research the complex will be specially formulated for bed-wetting.

Homoeopathic similimum: The similimum is a single remedy that most accurately reflects the state of the patient. Rather than being specific for a given complaint it reflects the state of the patient on the mental, emotional and physical plane. For this reason there are a number of remedies that can be used for bedwetting, each with an entirely different symptom picture.

Ilex Paraguayensis: Ilex Paraguayensis is a herb which is used for a tea in Paraguay. This herb when homoeopathically prepared is reputed to be effective in the treatment of bed-wetting.

Double blind study: A double blind study is one in which neither the researchers or the patients know the nature of the medication. For the purpose of this study this implies that neither patient nor researcher will know who is receiving placebo, complex, similimum or Ilex Paraguayensis.

Placebo: Sixteen patients out of sixty-six will receive placebo. For the purposes of this study the placebo will be non-medicated powders that have an identical appearance and taste to medicated powder. The use of placebo or a control in clinical trials is considered to be in keeping with the scientific method. Its main purpose is to provide a base line against which results can be measured. Patients who received placebo will be offered treatment free of charge after completion of the study.

Powders: The medication to be used will be dispensed in lactose powders (see example provided). These powders are sweet tasting and easy to use. The powders are to be administered in numerical order prior to going to sleep. The child should not eat, drink nor brush teeth fifteen minutes before or after administration.

Nocturnal enuresis: (bed-wetting) Nocturnal enuresis is the inability to maintain bladder control during sleep. It is a common disorder that is thought to be 80% psychogenic. Other causes of enuresis include chronic bladder infection, delayed maturation and neurological abnormalities. It is divided into primary and secondary types. Subjects who have never achieved voluntary bladder control are considered to fall into the primary type. Those who have had bladder control and then develop enuresis at a latter stage are considered to fall within the secondary type. Both categories of children will be considered.

Outline of study: The study will comprise sixty-six children. The supervisor will randomly divide them into four groups (similimum, complex, I. paraguayensis and control). Each child will receive a physical examination as well as have his / her case taken by the students. Part of the case taking will include interviewing the caregivers, particularly for the very young children. Once the case taking is complete there will be a two-week observation period during which the incidence of bedwetting will be noted. Thereafter the treatment period of two weeks will commence with each child receiving a single powder each evening before bed. Once this period is complete, post treatment observation of four weeks will commence with completion of enuresis diaries. Once the study is over children on placebo will be offered free treatment.

Enuresis diary: This will comprise a simple calendar that will be filled in with a yes/no answer each day by either the caregivers or the students.

Contact: The student researchers will be in regular contact with the caregivers and children. In addition they will be telephonically available, as will their supervisors.

Dr C Hall

Michael Bloch

Heather Lockyear

Paddy Reilley

Confidentiality: All data collected will be confidentially handled. The final thesis will be presented in such a way that the confidentiality of participants will be ensured.

Follow up: The aim of this project is to evaluate the use of homoeopathy in the treatment of enuresis, with the well being of the participants being of foremost importance. For this reason children who have improved or who wish to improve will be encouraged to attend our day clinic after the trial. The clinic offers a free service (consultation and medicine) to those willing to be observed.

Risks: Homoeopathic treatment has no side effects. For this reason it is an ideal treatment method and poses no risk to the user.

Benefits: The researchers hope that the participants will directly benefit from participating in this research. The research is aimed at reducing the incidence of nocturnal enuresis.

Costs: The research will be at no cost to participants or the children's' homes.



### **Appendix 3.1: Simplified patient information sheet**

We want to welcome you to our study. This page explains what we are doing in our study. It is important for you to understand that it is your choice to be in the study, and that you know how it works. This sheet gives you information about our study.

The reason we are doing this study is to see how homoeopathy works in bedwetting.

Bedwetting: Bedwetting is weeing in your bed at night.

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

Homoeopathic complex: The homoeopathic complex is a medicine made of a mixture of five different medicines. All of these medicines are used to treat bedwetting.

Ilex Paraguensis: A plant from South America used to treat bedwetting.

Placebo: Some children will get a placebo. A placebo is something that looks like a medicine but isn't a medicine. Children who get placebo will be given medicine at the end of the study.

Double blind study: This means that you do not know and the researcher will not know if you are given a placebo. This is done to make the study scientific.

Medicine: The medicine being used is given out in powders that we will show you. They are sweet tasting and easy to use. The powders are to be taken every night before going to bed. The powders are numbered, and are to be used in order e.g. 1,2,3 etc. You should not eat, drink or brush your teeth fifteen minutes before or after taking the powder. Your mouth must be clean. The powders should be put straight onto the tongue and do not need to be put in water.

The study: The study will last eight weeks. The first two weeks we will count the number of time that each child wets their bed. The next two weeks the children will get their medicine. The last four weeks we will again count the number of times that each child wets their bed. We will meet with each child and their house parent to get to know them.

Assent form: This is a form that each child must sign. This form makes sure that the children are not being forced to take part in the study.

Diary: Every day the house parent will tick off on a calendar whether the child wet their bed or not.

Telephone numbers: We can be phoned at the following telephone numbers.

- Dr C Hall
- Michael Bloch
- Heather Lockyear
- Paddy Reilly

We will visit you each week during the study.

Confidentiality: This means that all the information will be private and not shared with other people. It will also mean that at the end of the study no one, except us, your house parent and the principal of your home will know that you have been in this study.

### Appendix 3.2: Zulu translation of simplified patient information sheet

Siyakwamukela kulolucwaningo. Lelikhazi lichaza esikwenzayo kulolucwaningo. Kubalulekile ukuba wazi ukuthi ungenela lolucwaningo ngokuthanda kwakho, nokuthi ulwazi ukuthi lusebenza kanjani.

- Homeopathy:-** Uhlobo lwemithi yemvelo olusiza umzimba ukuba uzelaphe ngokwawo. Uphephile kubantwana.
- Homeopathy Complex:-** Uhlobo oluthile lomuthi olwenziwe ngengxube yemithi emihlanu. Lusetshenziswa ukwelapha ukuchama uma ulele.
- Homeopathic Similimum:-** Uhlobo lomuthi olukhethelwa lowo muntu olugondene naye, okusho ukuthi umntwana ngamunye uthola lowo muthi oqondene nesimo akuso.
- Ilex Paraguensis:-** Isitshalo esitholakala e South America eselapha ukuchama uma ulele.
- Placebo:-** Abanye abantwana bazonikezwa I placebo. I placebo into ebukeya sengathi umuthi, kodwa kungesiwo. Abantwana okudingeka banikezwe I placebo bayonikezwa ekupheleni kocwaningo.
- Double blind Study:-** Loku kusho ukuthi wena kanye nomcwaningi wophenyo angeke naziswe ukuthi unikezwe I placebo. Loku kwenzelwa ukuba ucwaningo lube lula kwezesayensi (scientific).
- Medicine:** Imithi enizoyinikezwa iyobe izimpushana. Inambitheka ngokusashukela, kulula futhi nokuyisebenzisa. Imithi lena kumele ithathwe zonke izinsuku ebusuku ngaphambi kokuba ulale. Imithi lena inezinombolo futhi kumele ithathwe ngokulandelana kwezinombolo e.g. 1,2,3...etc. Akumele udle, uphuze noma uwashe amazinyo imizuzu engu 15 ngaphambili noma ngemuva kokusebenzisa lempushana. Umlomo kumele uhlanzeke. Umuthi kumele umunyungwe ngolimi, asikho isidingo sokuwuxuba namanzi.
- Bedwetting:-** Ukuchama ebusuku uma ulele.
- The Study:-** Amasonto amabili okuqala sibala izikhathi umntwana azichamela ngazo ebusuku uma elele. Amasonto amabili alandelayo abantwana bazonikwezwa imithi (impushana). Amasonto alandelayo amane (4 weeks) siphinde sibale izikhathi umntwana azichamele ngazo ebusuku uma ulele. Sizohlangana nomntwana kanye nomzali ukuze sithole ukwazana nabo.

**Assent Form:-** Ifomu okumele umntwana ngamunye alisayine.  
Lelifomu lenzela ukuqinisekisa ukuthi akekho umntwana  
ophoqiwe ukuba angenele lolucwaningo.

**Diary:-** Zonke izinsuku umzali kumele abeke uphawu  
kwikhalenda oluchaza ukuba umntwana uchamile yini  
ngenkathi elele noma cha.

**Izinombolo zocingo:-** Sitholakala kulezizinambolo ezilandelayo:

- Dr C Hall -
- Michael Bloch
- Heather Lockyear
- Paddy Rielly

**Sizonivakashela wonke amasonto**

### **CONFIDENTIALITY:**

**LONKE ULWAZI OLUZOTHOLAKALA KULOLUCWANINGO LUYOBE  
LUYIMFIHLO, AKEKHO OMUNYE UMUNTU OZOLWAZI. AKUKHO  
MUNTU OZOKWAZI UKUTHI UBUNGOMUNYE WABANGENILE  
KULOLUCWANINGO.**

## Appendix 4: Homoeopathic case history

### PATIENT'S DETAILS

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

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

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

Sex: M/F      Consultation: initial / follow up

### PARENTS' DETAILS

Name of parent(s) / guardian(s) \_\_\_\_\_

Telephone (H) \_\_\_\_\_ (W) \_\_\_\_\_

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

PAST MEDICAL HISTORY AND TREATMENT: (including childhood diseases)

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Medication: \_\_\_\_\_

Vaccinations: \_\_\_\_\_

Allergies: \_\_\_\_\_

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

BIRTH HISTORY: Pregnancy \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Labour \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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

GENERALS:

Sleep: (patterns and positions) \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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

SYSTEMS REVIEW:

HEAD: \_\_\_\_\_  
\_\_\_\_\_

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

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

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

GIT: Feeding / diet \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Cravings and aversions \_\_\_\_\_  
\_\_\_\_\_

Appetite \_\_\_\_\_

Thirst \_\_\_\_\_

Stool (colour, consistency, frequency) \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

GENITO-URINARY: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Urine \_\_\_\_\_

Discharges \_\_\_\_\_

MUSCULOSKELETAL AND CNS: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

SKIN: \_\_\_\_\_

Perspiration \_\_\_\_\_  
\_\_\_\_\_

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

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

Fears \_\_\_\_\_  
\_\_\_\_\_

Comments and observations



## Appendix 5: Physical examination

### VITAL SIGNS:

Temperature \_\_\_\_\_ Pulse rate \_\_\_\_\_

Respiratory rate \_\_\_\_\_ BP \_\_\_\_\_

Height \_\_\_\_\_ Weight \_\_\_\_\_

### GENERAL EXAMINATION:

Jaundice/ anaemia/ cyanosis/ clubbing dehydration/ Odessa/  
lymphadenopathy

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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

\_\_\_\_\_  
\_\_\_\_\_

CHEST EXAMINATION: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

ABDOMINAL EXAMINATION: Abdominal masses, distension, sphincter tone

\_\_\_\_\_  
\_\_\_\_\_

NEUROLOGICAL EXAMINATION: Gait, reflexes, observation of spinal cord,  
dermatomes and myotomes L2, L3, L4, L5 \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

TESTS: Urine dipstick \_\_\_\_\_

## Appendix 6: Enuretic diary

**Week Eight**

Researcher:

Patient:

Care-giver/ cottage:

Mon	Tues	Wed	Thurs	Fri	Sat	Sun

**Week Seven**

Researcher:

Patient:

Care-giver/ cottage:

Mon	Tues	Wed	Thurs	Fri	Sat	Sun

**Week Six**

Researcher:

Patient:

Care-giver/ cottage:

Mon	Tues	Wed	Thurs	Fri	Sat	Sun

**Week Five**

Researcher:

Patient:

Care-giver/ cottage:

Mon	Tues	Wed	Thurs	Fri	Sat	Sun

**Week Four**

Researcher:

Patient:

Care-giver/ cottage:

Mon	Tues	Wed	Thurs	Fri	Sat	Sun

**Week Three**

Researcher:

Patient:

Care-giver/ cottage:

Mon	Tues	Wed	Thurs	Fri	Sat	Sun

**Week Two**

Researcher:

Patient:

Care-giver/ cottage:

Mon	Tues	Wed	Thurs	Fri	Sat	Sun

**Week One**

Researcher:

Patient:

Care-giver/ cottage:

## Appendix 7: Rubrics and repertory sheets

### Case 1

#### Script

Rx: Tuberculinum bovinum, 1/30CH, 2/200CH, 3/1M, 4-14/sac lac

Mitte: pulv. XIV

Sig: o.n.

#### Rubrics

HEAD; BEAT, beats; his or her own head; bed, against the

HEAD; KNOCKS against things

HEAD; PERSPIRATION; night

MIND; ANGER, irascibility; general; temper tantrums

MIND; BREAK things, desire to

MIND; DEFIANT

GENERALITIES; FOOD and drinks; milk; aversion

EARS; ERUPTIONS; general; behind

#### Repertory sheet

	Tub.	Calc.	Sulph.	Sil.	Staph.	Bell.	Merc.	Nux-v.	Puls.	Sep.	Bar-c.	Caust.	Ars.	Apis	Cina
Total	11	11	9	9	9	7	6	6	6	6	6	6	6	6	6
Rubrics	8	5	6	5	4	5	4	4	4	4	2	2	5	3	3
Family															
BEAT, beats; his or her own head;...	1												1	2	
HEAD; KNOCKS against things	3					3							1	1	
HEAD; PERSPIRATION; night	1	4	1	2			2			1			1		
ANGER, irascibility; general;...	1	1	1	1	2	1		2	1						1
MIND; BREAK things, desire to	2	1	1		1	1		2						2	
MIND; DEFIANT	1		1	1		1	1	1	1	1	3	3			2
FOOD and drinks; milk; aversion	1	2	2	2	3	1	1	1	2	2			1		2
EARS; ERUPTIONS; general; behind	1	3	3	3	3		2		2	2	3	3	1		



## Case 2

### Script

Rx: Calcarea carbonica 1-7/30CH, 8-14/sac lac  
Mitte: pulv: XIV  
Sig: o.n.

### Rubrics

HEAD; PERSPIRATION; night  
MIND; AILMENTS from; anger, vexation  
MIND; FASTIDIOUS  
SLEEP; POSITION; abdomen, on  
MIND; FEAR; general; ghosts, of  
HEAD; MOTIONS; of; general; nodding of  
GENERALITIES; FOOD and drinks; fruit; desires  
GENERALITIES; FOOD and drinks; fish; desires  
MIND; FEAR; general; animals, of; snakes, of  
GENERALITIES; INFLAMMATION; general; glands, adenitis

### Repertory sheet

	Calc.	Puls.	Nat-m.	Ars.	Phos.	Sulph.	Med.	Lyc.	Carc.	Bell.	Sep.	Calc-p.	Ign.	Acon.	Lach.
Total	13	13	12	11	11	11	10	10	9	9	8	8	8	8	7
Rubrics	8	7	8	8	7	7	7	6	6	5	7	6	5	4	5
Family															
HEAD; PERSPIRATION; night	4		1	1		1	1				1	1			
AILMENTS from; anger, vexation	1	2	2	2	2	1		2	1	2	1	2	3	3	2
MIND; FASTIDIOUS		3	2	2	1	1	1		3		1	1			
SLEEP; POSITION; abdomen, on	1	2		1	1	2	3	2	2	2	2	2	1		1
MIND; FEAR; general; ghosts, of	1	2	1	2	2	2	1	2	1	1	1			2	
MOTIONS; of; general; nodding of	1		2					1			1		1		
FOOD and drinks; fruit; desires	1	1	1	1	1		1		1				2		1
FOOD and drinks; fish; desires			2		1		2	1				1		1	
FEAR; general; animals, of; snakes, of	1	1	1	1		1			1	1	1		1		2
INFLAMMATION; general; glands,...	3	2		1	3	3	1	2		3		1		2	1

### Case 3

#### Script

Rx: Sulphur, 1-3/30CH, 4/200CH, 7-14/sac lac  
Mitte: pulv XIV  
Sig: o.n.

#### Rubrics

MIND; MOOD; alternating  
SLEEP; POSITION; abdomen, on  
MIND; DICTATORIAL, domineering, dogmatic, despotic  
MIND; STRANGER, strangers; presence of; agg.  
GENERALITIES; FOOD and drinks; milk; aversion  
URINE; ODOR; acrid, pungent  
GENERALITIES; WARMTH; agg.  
MIND; COMPANY; desire for  
MIND; ANSWER, answering, answers; refuses to

#### Repertory sheet

	Total	Phos.	Sulph.	Lyc.	Stram.	Puls.	Bell.	Sep.	Ars.	Calc.	Camph.	Ign.	Caust.	Merc.	Arn.	Bry.
Rubrics	9	8	7	7	6	8	7	8	6	5	5	8	8	5	5	5
Family																
MIND; MOOD; alternating (109)	2	2	3	2	2	3	1	1	1		3	1	1	1		
SLEEP; POSITION; abdomen, on (40)	1	2	2	2	2	2	2	1	1		1	1				1
DICTATORIAL, domineering, ...(37)	1	1	2			1		1		2		1	2	1		
STRANGER, strangers; ...(19)	1		1	2			2					1				2
FOOD and drinks; milk; aversion (79)	2	2		1	2	1	2	1	2		2		1	2	2	
URINE; ODOR; acrid, pungent (49)	1	2	2	1	1	1	1	1	2	1		1	1			
GENERALITIES; WARMTH; agg. (175)	2	3	2		3	1	1	1	2	2	1	1	2	2		2
MIND; COMPANY; desire for (121)	4	1	3	2	2	1	2	3	2	2	2	1	1			1
ANSWER, answering, answers; ...(33)	3	3		2		1		1		2		1		2		

## Case 4

### Script

Rx: Tuberculinum bovinum, 1-3/200CH, 4-14/ Belladonna 30CH  
 Mitte: pulv. XIV  
 Sig: o.n.

### Rubrics

MIND; IDIOCY

BLADDER; URINATION; involuntary; night, incontinence in bed; sleep; first, in

MIND; THROWS; things; persons, at

GENERALITIES; GLANDS in general, complaints of

MIND; IRRITABILITY; general; waking, on; agg.

MIND; FEAR; general; dark

MIND; ANGER, irascibility; general; temper tantrums

### Repertory sheet

	Tub.	Bell.	Phos.	Puls.	Lyc.	Caust.	Lach.	Ph-ac.	Sep.	Calc.	Sulph.	Ars.	Staph.	Sil.	Bar-c.
Total	10	8	8	8	8	7	7	6	6	6	6	6	5	5	5
Rubrics	7	6	5	5	4	5	4	4	4	3	5	4	4	3	2
Family															
MIND; IDIOCY	2	1	2		1	1	2	1			1	1			2
URINATION; involuntary; night,...	1		1	1		3		2	3						
MIND; THROWS; things; persons, at	1	1											1		
GLANDS in general, complaints of	1	2	2	3	2	1	2	1	1	3	1	1	1	3	3
IRRITABILITY; general; waking, on;...	3	2		1	3	1	2	2	1		1	2	1		
MIND; FEAR; general; dark	1	1	2	2	2	1			1	2	1	1		1	
ANGER, irascibility; general;...	1	1	1	1			1			1	1		2	1	



## Case 5

### Script

Rx: Suphur 1-3/30CH, 4-14/sac lac

Mitte: pulv. XIV

Sig: o.n.

### Rubrics

FACE; ERUPTIONS; general; eyes; about

GENERALITIES; ERUPTIONS; agg., suppressed

MIND; DICTATORIAL, domineering, dogmatic, despotic

SPEECH & VOICE; VOICE; loud

GENERALITIES; FOOD and drinks; farinaceous food, starchy; aversion

BACK; ERUPTIONS; eczema; cervical region

### Repertory sheet

	Sulph.	Ars.	Lyc.	Caust.	Sep.	Merc.	Petr.	Sil.	Bell.	Bry.	Dulc.	Staph.	Cham.	Camph.	Graph.
Total	10	8	7	6	6	6	6	5	5	5	5	5	4	4	4
Rubrics	6	5	4	4	4	3	3	4	3	2	2	2	3	2	2
Family															
ERUPTIONS; general; eyes; about	3	2		2	1	3	1	1		2		3			2
ERUPTIONS; agg., suppressed	3	3	2	2	2	1	3	1	2	3	3	2	2	2	2
DICTATORIAL, domineering,...	1	1	2	1		2			1		2		1	2	
SPEECH & VOICE; VOICE; loud	1	1			1			1	2				1		
FOOD and drinks; farinaceous food,...	1	1	1												
ERUPTIONS; eczema; cervical region	1		2	1	2		2	2							

## Case 6

### Script

Rx: Pulsatilla pratensis; 1/200CH, 2/1M, 3/10M, 4-14/sac lac  
Mitte: pulv. XIV  
Sig: o.n.

### Rubrics

MIND; HOME; desires to; go  
MIND; FORSAKEN feeling  
MIND; AILMENTS from; grief, sorrow, care  
BLADDER; URINATION; involuntary; children, in  
SLEEP; POSITION; back, on  
MIND; WEeping, tearful mood; general; trifles, at  
URINE; ODOR; acrid, pungent

### Repertory sheet

	Puls.	Calc.	Rhus-t.	Bry.	Lyc.	Sulph.	Aur.	Caust.	Lach.	Stram.	Nat-m.	Plat.	Sep.	Verat.	Psor.
Total	12	11	9	9	8	8	8	8	8	7	7	7	6	6	6
Rubrics	7	7	6	3	6	6	4	4	4	5	4	4	5	5	4
Family															
MIND; HOME; desires to; go (39)	1	2	1	3					2					1	1
MIND; FORSAKEN feeling (104)	3	1	1		1	1	3		2	2	2	2	1	1	3
AILMENTS from; grief, sorrow ...(88)	2	2	1	3	1	1	3	3	3	1	3	2	2	1	1
URINATION; involuntary; ...(26)	1	1	1		1	1		1					1		1
SLEEP; POSITION; back, on (88)	3	2	3	3	2	2	1		1	2	1	2		1	
WEeping, tearful mood; ...(41)	1	1			1	1	1	3		1	1	1	1	2	
URINE; ODOR; acrid, pungent (49)	1	2	2		2	2		1		1			1		



## Case 7

### Script

Rx: Lac canium 1-14/30CH  
Mitte: pulv XIV  
Sig: o.n.

### Rubrics

MIND; DELUSIONS, imaginations; animals, of; snakes; in and around her  
MIND; DREAMS; urinating, of  
MIND; FEAR; general; dark  
BLADDER; URINATION; involuntary; night, incontinence in bed  
BLADDER; URINATION; involuntary; adolescence, in

### Repertory sheet

	Lac-c.	Bell.	Stram.	Sep.	Arg-n.	Calc.	Sulph.	Tub.	Hyos.	Lyc.	Op.	Gels.	Kreos.	Puls.	Acon.
Total	8	6	6	5	5	5	5	5	4	4	4	3	5	5	4
Rubrics	5	4	3	3	3	3	3	3	3	3	3	3	2	2	2
Family	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
DELUSIONS, imaginations; animals,...	2	1	2		1	1		1	2		1	1			
MIND; DREAMS; urinating, of	1	1		2			1			1			2		
MIND; FEAR; general; dark	1	1	4	1	1	2	1	1	1	2	1	1		2	2
URINATION; involuntary; night,...	3	3	2	3	3	2	3	3	1	1	2	1	3	3	2
URINATION; involuntary;...	1														

## Case 8

### Script

Rx: Thuja occidentalis 1-3/200CH, 4-14/sac lac  
Mitte: pulv XIV  
Sig: o.n.

### Rubrics

BLADDER; URINATION; involuntary; daytime  
BLADDER; URINATION; involuntary; night, incontinence in bed  
GENERALITIES; FOOD and drinks; onions; aversion  
MIND; RESERVED  
MIND; FORSAKEN feeling; isolation, sensation of  
MIND; DECEITFUL, sly  
MIND; INJUSTICE, cannot support  
MIND; INDIFFERENCE, apathy; duties, to

### Repertory sheet

	Thuja.	Sep.	Merc.	Arg-n.	Calc.	Ars.	Nat-m.	Op.	Sulph.	Nux-v.	Phos.	Bell.	Fl-ac.	Puls.	Caust.
Total	9	5	7	9	9	8	8	7	7	5	8	7	7	7	6
Rubrics	7	6	6	5	5	5	5	5	5	5	4	4	4	4	4
Family															
URINATION; involuntary; daytime	1			2		1				1		2	3		1
URINATION; involuntary; night,...	2	3	2	3	2	3	3	2	3	1	2	3	2	3	3
FOOD and drinks; onions; aversion	2	1						1			2				
MIND; RESERVED	1	1	1	1	2	1	1	1	1	1	3	1	1	2	1
FORSAKEN feeling; isolation,...	1		1	2				1						1	
MIND; DECEITFUL, sly	1	1	1	1	1	2	2	2	1	1		1	1	1	
MIND; INJUSTICE, cannot support	1	1	1		1		1		1	1	1				1
INDIFFERENCE, apathy; duties, to		1	1		3	1	1		1						

## Case 9

### Script

Rx: Pulsatilla pratensis 1-3/30Ch, 4-6/200Ch, 7-9/1M, 10-14/sac lac  
Mitte: pulv XIV  
Sig: o.n.

### Rubrics

GENERALITIES; FOOD and drinks; spices, condiments, piquant, highly seasoned food; aversion  
MIND; SYMPATHETIC, compassionate  
MIND; FEAR; general; ghosts, of  
MIND; WEeping, tearful mood; general; anger; after  
MIND; WEeping, tearful mood; general; easily  
MIND; SENSITIVE, oversensitive; general; children  
MIND; SENSITIVE, oversensitive; general; reprimands, criticism, reproaches, to  
MIND; FEAR; general; animals, of; snakes, of

### Repertory sheet

	Puls.	Nat-m.	Caust.	Bell.	Carc.	Phos.	Calc.	Med.	Staph.	Nux-v.	Plat.	Ign.	Lyc.	Sep.	Chin.
Total	12	9	9	8	8	8	7	6	6	6	6	5	5	5	4
Rubrics	8	7	5	6	6	4	6	5	5	4	4	4	4	4	1
Family															
FOOD and drinks; spices, ...(9)	1					1									
SYMPATHETIC, compassionate (61)	1	2	2	1	2	3	1	1	1	2		2	1	1	1
MIND; FEAR; general; ghosts, of (42)	2	1	2	1	1	2	1	1			2		2	1	1
WEeping, tearful mood; ...(16)	1	1	1	1					1	2	2				
WEeping, tearful mood; ...(34)	3	2	3	2	1		2	1	1		1		1	2	1
SENSITIVE, oversensitive; ...(33)	2	1	1	2	1	2	1	1	2	1	1	1	1		1
SENSITIVE, oversensitive; ...(29)	1	1			2		1	2	1	1		1			
FEAR; general; animals, of; ...(19)	1	1		1	1		1					1		1	

## Case 10

### Script

Rx: Sulphur 1-3/30CH, 4-5/200CH, 6/1M, 7-14/sac lac  
 Mitte: pulv XIV  
 Sig: o.n.

### Rubrics

MIND; FEAR; general; robbers, of  
 HEAD; PERSPIRATION; sleep; during  
 RECTUM; DIARRHEA; general; milk; agg.  
 EXTREMITIES; HEAT; general; lower limbs; feet; uncovers feet  
 MIND; DREAMS; urinating, of  
 MIND; FEAR; general; ghosts, of; night  
 BLADDER; URINATION; involuntary; night, incontinence in bed

### Repertory sheet

	Total	sulph.	Sep.	Sil.	Calc.	Lyc.	Ars.	Puls.	Mag-m.	Merc.	Cham.	Mag-c.	Sanic.	Lach.	Med.	Nat-c.
MIND; FEAR; general; robbers, of	13	12	10	10	9	9	9	7	7	7	5	5	6	6	6	6
HEAD; PERSPIRATION; sleep; during	7	5	5	4	5	4	4	4	4	3	4	4	3	3	3	3
RECTUM; DIARRHEA; general; milk; agg.	2	3	2	3	2	1	1	3			2					3
EXTREMITIES; HEAT; general; lower limbs; feet; uncovers feet	3	2	2	2			3	1	1	3	2	2	3	3		
MIND; DREAMS; urinating, of	1	2			1											
MIND; FEAR; general; ghosts, of; night	2				2	1	2									
BLADDER; URINATION; involuntary; night, incontinence in bed	3	3	3	2	1	3	3	2	2	2	1	2	1	2	2	2

## Case 11

### Script

Rx: Strammonium datura, 1-3/200CH, 4/10M, 5-14/sac lac

Mitte: pulv XIV

Sig: o.n.

### Rubrics

MIND; CLIMB, desire to

MIND; HOLDING or being held; desire

MIND; TOUCHED; aversion of being

SPEECH & VOICE; SPEECH; stammering

EXTREMITIES; RESTLESSNESS; upper limbs; hands

URINE; ODOR; acrid, pungent

### Repertory sheet

	Stram.	Bell.	Ars.	Sulph.	Lach.	Nux-v.	Tarent.	Phos.	Merc.	Arn.	Kali-br.	Plb.	Ant-t.	Calc.	Gels.
Total	5	8	7	7	7	6	6	5	5	5	5	4	4	4	4
Rubrics	5	5	5	4	3	3	2	4	3	2	2	4	3	3	3
Family															
MIND; CLIMB, desire to	1	1													
HOLDING or being held; desire for	2		2	2	3	2		1				1	1		2
MIND; TOUCHED; aversion of being	1	2	1		2	1	3		1	3		1	2	1	1
SPEECH; stammering	3	3	1	2	2	3		2	3	2	2	1			1
RESTLESSNESS; upper limbs; hands	1	1	2	1			3	1			3	1		1	
URINE; ODOR; acrid, pungent	1	1	1	2				1	1				1	2	

## Case 12

### Script

Rx: Medorrhinum, 1-3/200CH, 4-14/placebo

Mitte: pulv XIV

Mitte: o.n.

### Rubrics

MIND; FEAR; general; ghosts, of

MIND; ACTIVITY; general; hyper active

BLADDER; URINATION; involuntary; night, incontinence in bed

MIND; DESTRUCTIVENESS

MIND; CURSING, swearing; desires

SLEEP; POSITION; abdomen, on

MIND; DECEITFUL, sly

MIND; THOUGHTS; general; persistent; sexual

### Repertory sheet

	Med.	Stram.	Hyos.	Bell.	Cupr.	Phos.	Carc.	Gall-ac.	Op.	Sep.	Calc.	Tarent.	Tub.	Sulph.	Ars.
Total	13	14	11	14	7	11	6	3	8	10	8	7	9	5	10
Rubrics	6	7	7	8	5	7	5	3	6	7	7	5	4	6	5
Family															
MIND; FEAR; general; ghosts, of	1	2	2	1		2	1	1	1	1	1			2	2
ACTIVITY; general; hyper active	2	1	1	2		2			1	1		1			
URINATION; involuntary; night,...	2	2	1	3	1	2	1		2	3	2		3	3	3
MIND; DESTRUCTIVENESS	1	4	2	2	2	1	1	1	1		1	2	2	1	
MIND; CURSING, swearing; desires	1	1	2	2	1	1	1	1	1	1	1	1	2		2
SLEEP; POSITION; abdomen, on	3	2		2	1	1	2			2	1		1	2	1
MIND; DECEITFUL, sly	2		2	1	2				2	1	1	2		1	2
THOUGHTS; general; persistent;...	1	2	1	1		2				1	1	1		1	

# Case 13

## Script

Rx: Tuberculinum bovinum 1-3/30CH, 4-6/200CH, 7/1M, 8-14/sac lac  
Mitte: pulv XIV  
Sig: o.n.

## Rubrics

MIND; WANDER; desires to  
HEAD; BEAT, beats; his or her own head; bed, against the  
SLEEP; POSITION; abdomen, on  
SLEEP; POSITION; knees; on; elbows, and  
MIND; DISOBEDIENCE  
MIND; MISCHIEVOUS  
EXTREMITIES; HEAT; general; lower limbs; feet; uncovers feet

## Repertory sheet

	Tub.	Calc.	Med.	Lach.	Phos.	Stram.	Merc.	Puls.	Sep.	Cham.	Calc-p.	Sulph.	Tarent.	Ars.	Ign.
Total	10	9	9	8	7	7	7	7	7	7	6	6	6	5	5
Rubrics	6	6	3	5	5	5	4	4	4	3	4	3	3	4	1
Family															
MIND; WANDER; desires to	3	1		1			1				2				
BEAT, beats; his or her own head;...	1					1							1	1	
SLEEP; POSITION; abdomen, on	1	1	3	1	1	2		2	2		2	2		1	1
POSITION; knees; on; elbows, and	2	2	3		2	1		1	2		1			1	1
MIND; DISOBEDIENCE	2	1		1	1	1	3		1	1	1	1	3		
MIND; MISCHIEVOUS	1	2		2	1	2	2	1		3			2	2	1
HEAT; general; lower limbs; feet;...		2	3	3	2		1	3	2	3		3			2

# Case 14

## Script

Rx: Pulsatilla pratensis 1-3/30CH, 4-6/200CH, 7/1M, 8-14/sac lac  
Mitte: pulv XIV  
Sig: o.n.

## Rubrics

MIND; RESPONSIBILITY; strong  
SLEEP; FALLING asleep; difficult  
SLEEP; SLEEPLESSNESS; general; children, in  
SLEEP; POSITION; back, on; hand; over the head  
MIND; SYMPATHY, compassion; desire for  
MIND; FASTIDIOUS  
MIND; FORSAKEN feeling  
MIND; DISTURBED, averse to being

## Repertory sheet

	Puls.	Carc.	Nat-m.	Phos.	Sulph.	Ars.	Bamb-a.	Nat-c.	Mag-m.	Aur.	Hell.	Nux-v.	Plat.	Lyc.	Sil.
Total	13	11	9	9	6	6	6	6	5	5	5	5	5	4	4
Rubrics	7	7	6	5	5	4	4	4	4	3	3	3	3	4	4
Family															
MIND; RESPONSIBILITY; strong	1	1	1				2		1	1				1	
SLEEP; FALLING asleep; difficult		1	1	2	2			2	1					1	1
SLEEPLESSNESS; general; children, in	1	3		1		2	2		2					1	
POSITION; back, on; hand; over the...	3	1			1	1						1	2		
SYMPATHY, compassion; desire for	1	1	1	4				1			3				
MIND; FASTIDIOUS	3	3	2	1	1	2		1		1		2	1		1
MIND; FORSAKEN feeling	3	1	2		1	1	1	2	1	3	1		2	1	1
MIND; DISTURBED, averse to being	1		2	1	1		1				1	2			1



## Case 15

### Script

Rx: Carcinosinum 1-3/200CH, 4-7/sac lac, 8-14/Phosphorous 30CH  
 Mitte: pulv. XIV  
 Sig: o.n.

### Rubrics

BLADDER; URINATION; involuntary; night, incontinence in bed; sleep; first, in  
 EXTREMITIES; WARTS; general; upper limbs; fingers  
 MIND; FASTIDIOUS  
 GENERALITIES; FOOD and drinks; onions; aversion  
 GENERALITIES; FOOD and drinks; vegetables; desires  
 MIND; SYMPATHETIC, compassionate  
 MOUTH; FINGERS in the mouth, children put  
 MIND; DREAMS; dead; people, of  
 HEAD; BEAT, beats; his or her own head; bed, against the  
 MIND; SENSITIVE, oversensitive; general; reprimands, criticism, reproaches,  
 MIND; DREAMS; dead; bodies

### Repertory sheet

	Ars.	Phos.	Sep.	Med.	Calc.	Nat-m.	Caust.	Thuj.	Lyc.	Sulph.	Carc.	Nux-v.	Puls.	Nat-s.	Aur.
Total	10	10	10	9	9	9	9	9	8	8	8	7	7	6	6
Rubrics	7	6	6	7	6	6	5	5	6	6	4	5	5	6	4
Family															
URINATION; involuntary; night,...		1	3				3						1		
WARTS; general; upper limbs; fingers	1		2		2	2	2	2	1	1				1	
MIND; FASTIDIOUS	2	1	1	1		2		1		1	3	2	3	1	1
FOOD and drinks; onions; aversion		2	1	1				2	1						
FOOD and drinks; vegetables; desires	1									2					
MIND; SYMPATHETIC, compassionate		3	1	1	1	2	2		1		2	2	1		1
FINGERS in the mouth, children put				1	2	1			1	1				1	
MIND; DREAMS; dead; people, of	3	2		2	2		1	3	1	2		1		1	1
BEAT, beats; his or her own head;...	1														
SENSITIVE, oversensitive; general;...	1			2	1	1					2	1	1	1	
MIND; INDUSTRIOUS, mania for work	1	1	2	1	1	1	1	1	3	1	1	1	1	1	3

## Case 16

### Script

Rx: Sulphur 1-3/200CH, 4-14/sac lac  
Mitte: pulv. XIV  
Sig: o.n.

### Rubrics

GENERALITIES; BATHING, washing; aversion to, dread of  
MIND; WASHING; aversion to  
MIND; REMORSE; general  
MIND; REPROACHES; himself  
URINE; ODOR; acrid, pungent  
PERSPIRATION; ODOR; offensive  
BLADDER; URINATION; involuntary; night, incontinence in bed  
MIND; DICTATORIAL, domineering, dogmatic, despotic

### Repertory sheet

	Sulph.	Merc.	Puls.	Bell.	Lyc.	Phos.	Con.	Sep.	Am-c.	Ars.	Calc.	Sil.	Carb-v.	Nit-ac.	Staph.
Total	17	12	15	12	11	9	8	15	11	11	11	11	10	10	10
Rubrics	3	3	7	7	7	7	7	6	6	6	6	6	6	6	6
Family															
BATHING, washing; aversion to,...	3	1	2	2	1	1	2	3	3		2	1	2	1	2
MIND; WASHING; aversion to	3	1	2	2	1	1	1	3	3		2	1	2	1	2
MIND; REMORSE; general	1	1	2	2		1	1	2	1	2	2	2	1	1	1
MIND; REPROACHES; himself	1	1	2		1		1			2		1			
URINE; ODOR; acrid, pungent	2	1	1	1	2	1		1	1	1	2		1	1	1
PERSPIRATION; ODOR; offensive	3	3	3	1	3	2	1	3	1	2	1	3	2	3	2
URINATION; involuntary; night,...	3	2	3	3	1	2	1	3	2	3	2	3	2	3	2
DICTATORIAL, domineering,...	1	2		1	2	1	1			1					

**Appendix 8: Side effects of allopathic drugs commonly used in the treatment of nocturnal enuresis**

Imipramine hydrochloride (Tofranil ®):

Insomnia

Personality changes

Nervousness

Danger of overdose

Oxybutin chloride (Ditropan ®):

Constipation

Dizziness

Tremors

Desmopressin acetate (DDVAP):

Weight gain

Convulsions

Coma

Headaches

Allergic skin reactions

Serum sodium loss if there is not a restricted water intake