

**A comparison of the efficacy of two Homoeopathic interventions in the treatment of Primary Hypertension in adult females.**

By

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I, Raeesa Aboobaker, do hereby declare that this dissertation represents my own work in concept and execution.

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## **ABSTRACT**

### **INTRODUCTION**

Hypertension is a serious problem in South Africa, affecting 18.8 percent of women (South African Demographic and Health Survey, 2003), prompting investigation into treatment. In total, approximately 6.1 million people suffer from Hypertension in South Africa.

### **AIM**

The purpose of this double-blind study was to evaluate the efficacy of the Homoeopathicsimillimum and a Homoeopathic complex (*Aurummetallicum*6CH, *Lachesismuta*6CH, *Natrummuriaticum*6CH, and *Veratrum album* 6CH) in the treatment of Primary Hypertension in adult females.

### **METHODOLOGY**

A minimum of 30 patients were recruited and were selected on the basis of specified inclusion and exclusion criteria, and randomly divided into two equal groups by the research supervisor, with the first group receiving the Homoeopathic simillimum andthe second group receiving the Homoeopathic complex.The initial consultation took place at the Durban University of Technology or at the Umlazi Medical Centre after obtaining informed consent from the patients (Appendix D).A detailed case history was taken, followed by a complete physical examination, including blood pressure readings and cardiovascular system examinations.

Follow up consultations occurred weekly for a period of four weeks to record blood pressure readings, any changes in the general health and well being of the participants, in order to prescribe more medicines if needed.

A mercury sphygmomanometer and a Littmann Classic 2 stethoscope were the tools of measurement and was used according to the method outlined by Bates (2007), which states that an accurate measurement of blood pressure is dependent on the appropriate cuff size of the sphygmomanometer and whether the type of gauge used needs to be calibrated or not.

SPSS version 18 was used to analyse the data. A p value <0.05 was considered as statistically significant. Repeated measures ANOVA tests were done to compare the

blood pressures over time between the treatment groups. Specific remedies used at each time point were described by treatment group. Potencies of the remedies were compared within each remedy between the treatment groups using Pearson's chi square tests.

## **RESULTS**

Within each of the two treatment groups there was a highly significant decrease in systolic blood pressure over time ( $p < 0.001$ ). This means that both treatments were effective at lowering systolic blood pressure.

Within each of the two treatment groups there was a highly significant decrease in diastolic blood pressure over time ( $p = 0.001$  and  $p < 0.001$  respectively). This means that both treatments were effective at lowering diastolic blood pressure.

Systolic and diastolic blood pressures at five time points were compared between the two treatment groups using repeated measures ANOVA. There was an overall significant change over time in both groups ( $p < 0.001$ ), but the change over time was not different according to treatment groups ( $p = 0.355$ ). The decrease in systolic blood pressure over time was nearly identical in the two groups as the profiles are almost parallel. Therefore in terms of systolic blood pressure there was no statistical evidence for one treatment being more beneficial than the other.

There was an overall significant change over time in both groups ( $p < 0.001$ ) but the change over time was not different according to treatment groups ( $p = 0.187$ ). The decrease in diastolic blood pressure over time was almost the same rate in both groups as the profiles are almost parallel. Therefore in terms of diastolic blood pressure there was no statistical evidence for one treatment being more beneficial than the other.

## **CONCLUSION**

The results of the study led to the conclusion that both the simillimum and complex treatments were effective at reducing blood pressure over time, but there was no evidence that one treatment was more beneficial than the other, since the rates of change over time in systolic and diastolic blood pressure were similar in both treatment groups.

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## **DEFINITION OF TERMS**

### **Ascending potencies**

Potencies of remedies prescribed in such a method that the lowest potency is given first going up to end with the highest potency (De Schepper, 2005).

### **Blood pressure:**

#### **Systolic blood pressure**

Maximum arterial pressure at the time of contraction of the left ventricle of the heart and is the first number recorded when taking blood pressure (Mosby, 2002).

#### **Diastolic blood pressure**

Minimum arterial pressure when the heart relaxes and dilates and is the second and lower number recorded when taking blood pressure (Mosby, 2002).

### **Centesimal scale “cH”**

A method of potentising based on the principle that the first potency contains one hundredth part of the base substance and each succeeding potency contains one hundredth of the one immediately preceding (Centesimal potencies are denoted by suffixing “C” to the numerals denoting the deconcentration stage of the drug) (Gaier, 1991: 448).

### **Complex**

Simultaneous prescription of two or more remedies to treat a particular disease. This form of prescription entails no individualisation, as many patients suffering from a condition will receive the same medicine (O'Reilly, 2001).

### **M scale**

1 millesimal is equivalent to 1000cH

### **Plussed potency**

Ten impregnated granules are added to a 25ml dropper bottle followed by 18mls of purified water. The bottle is then swirled to dissolve the granules and once completely dissolved 2,5mls of 96 percent alcohol is added. The bottle is then sealed and succussed ten times and fixed with a label with the appropriate instructions. This

selection of potency provides for little or no aggravation and can be taken more often (De Schepper, 2005).

### **Potency**

The power, vitality, strength, or dynamis which a Homoeopathic remedy possesses, often represented as a number attached to the remedy name, either immediately before or after. The potency of the remedy comes as a result of the succession step in the remedy preparation process (Yasgur, 1998:193).

### **Simillimum**

Gaier (1991:509) defines the simillimum as the single Homoeopathic medicine, the drug picture of which most nearly approaches the total symptom complex of the patient, which will cure the patient, if the patient's condition is within reversible limits.

**CHAPTER 1**  
**INTRODUCTION**

According to the United States Department of Health, Joint National Committee's seventh report (2003), Hypertension is defined as an elevated blood pressure where systolic blood pressure is greater than 140mmHg and the diastolic blood pressure is greater than 90mmHg, on the average of two or more readings taken in the seated position, on two or more consecutive visits and where patients are at risk for end organ damage (Chobanian, Bakris, Black, Cushman, Green, Izzo, Jones, Materson, Oparil, Wright, and Rocella, 2003).

According to the South African Demographic and Health Survey (2003), 8.8 percent of South African men and 18.8 percent of women are hypertensive. These statistics infer that Hypertension is a serious problem, prompting investigation into treatment. Untreated Hypertension may remain asymptomatic for a long period of time, and may progress to Malignant Hypertension.

According to Hahnemann, Homoeopathy is a form of medicine based on the principle of '*similia similibus curentur*' i.e. 'like cures like', and whose medicines, in the form of remedies, acts to alter the body's deranged life force, to return it to a normal healthy state. It is when this life force or vital force becomes deranged that a diseased state manifests. Remedies are prescribed to the patient in minute doses that is enough to ameliorate the patient's symptoms without any adverse effects (O' Reilly, 2001).

**1.2 PROBLEM STATEMENT**

The purpose of this double-blind study was to evaluate the efficacy of the Homoeopathic simillimum and a Homoeopathic complex (*Aurum metallicum* 6CH, *Lachesis muta* 6CH, *Natrum muriaticum* 6CH, and *Veratrum album* 6CH) in the treatment of Primary Hypertension in adult females.

**1.3 HYPOTHESES**

1. The Homoeopathic simillimum lowers blood pressure in females that are not currently on any form of treatment.

2. The Homoeopathic complex lowers blood pressure in females that are not currently on any form of treatment.
3. A significant difference exists between the treatment effect of the Homoeopathic simillimum and the Homoeopathic complex.

#### **1.4 ASSUMPTIONS**

- Participants regularly took their medication as prescribed
- Participants did not have a change in lifestyle or resort to any other form of curative treatment for their symptoms of Hypertension for the duration of the study

#### **1.5 DELIMITATIONS**

- The treatment effect was not tested on a male population
- The treatment effect was not tested on females above the age of 65 as they were considered to be at a higher risk of organic disease and may consequently suffer from Secondary Hypertension.
- The treatment effect was not tested on patients who suffered from Malignant Hypertension
- The treatment effect was not tested on patients with Secondary Hypertension or endocrine disease.

Scientific literature proposes that research is continually conducted into the treatment of Hypertension. Vast amounts of money and time are invested by pharmaceutical companies to design new drugs, which may still produce unwanted side effects. By conducting a case study using the Homoeopathic simillimum and a Homoeopathic complex, one was able to determine whether Homoeopathic treatment produced a positive effect on Primary Hypertension.

## **CHAPTER 2**

### **REVIEW OF RELATED LITERATURE**

#### **2.1 DEFINITION**

Hypertension is defined as an elevated blood pressure where systolic pressure is greater than 140mmHg and the diastolic pressure is greater than 90mmHg on the average of two or more readings taken in the seated position, on two or more consecutive visits and where patients are at risk for end organ damage (Chobanian *et al.*, 2003).

#### **2.2 AETIOLOGY**

Hypertension can be categorised according to its aetiology. Primary Hypertension, which accounts for about 95 percent of cases, has no known cause (Boon, College, Walker and Hunter, 2006), whereas Secondary Hypertension, found in about five percent of cases, is due to an underlying disease such as alcoholism, obesity, pregnancy, renal disease, endocrine disease, cardiovascular disease, neurological disease or has an iatrogenic cause (Boon *et al.*, 2006).

##### **2.2.1 CLASSIFICATION OF HYPERTENSION**

According to the United States Department of Health Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and treatment of High Blood Pressure (2003), Hypertension is defined as a blood pressure greater than or equal to 140/90 mmHg. Normal blood pressure is said to be less than 120/80 mmHg

Table 2.1. Blood Pressure Classification

BP classification	Systolic BP (mmHg)	Diastolic BP (mmHg)
Normal	< 120	And < 80
Prehypertensive	120 – 139	Or 80 – 90
Stage 1 Hypertension	140 – 159	Or 90 – 99
Stage 2 Hypertension	≥ 160	Or ≥ 100

In the table above, classification is based on readings taken on two or more seated BP readings on two or more occasions (Chobanian *et al.*, 2003).

According to Kaplan (2005), the following factors may contribute to Primary Hypertension:

- **Genetics:**  
Studies conducted on family members with a family history of Hypertension, provide evidence that there is a genetic contribution to Hypertension, thus rendering some individuals as genetically susceptible to the condition.
  
- **Sodium intake:**  
An increase in blood pressure is directly related to an increase of sodium intake, which is mainly consumed as table salt. Furthermore, antihypertensive therapy, such as diuretics, may have a decreased effect if there is an excess of sodium in the body.
  
- **Stress:**  
An increase in the activity of the sympathetic nervous system, as caused by stress, leads to an elevation of blood pressure.
  
- **Obesity:**  
Weight gain and obesity are associated with an increase in blood pressure. A contributing factor in obesity is sleep apnoea, which results in hypoxemia and activation of the sympathetic nervous system, which in turn elevates blood pressure. The consumption of foods that are rich in saturated fats and cholesterol exacerbate weight gain and also disturbs endothelium dependent vasodilation through arteriosclerosis.
  
- **Alcohol consumption:**  
Alcohol consumed in large amounts, increases blood pressure through the sympathetic nervous system as well as by damaging cells and vital organs, such as the liver and the kidney, which assist in the control of blood pressure.



- Smoking:  
Smoking leads to a rise in blood pressure through damage to the blood vessels and the development of arteriosclerosis. It is thought that this occurs through the nicotine induced release of norepinephrine from adrenergic nerve endings.

### **2.3 EPIDEMIOLOGY**

According to the South African Demographic and Health Survey (2003), 8.8 percent of South African men and 18.8 percent of women are Hypertensive. This equates to 6.1 million people suffering from Hypertension in the South African population. It was noted that men and women reported suffering from high blood pressure most frequently when compared to other chronic conditions.

The survey found that in Kwa-Zulu Natal alone, 6.2 percent of males and 11.2 percent of females, aged 15 and older suffered from high blood pressure. In males and females, the prevalence of high blood pressure increased greatly from the age of 35 onward. Furthermore it was established that 33.5 percent of females between suffered from high blood pressure. The female respondents having high blood pressure consisted of 20.7 percent residing in an urban setting and 15.1 percent residing in a rural setting.

Hypertensive patients over the age of 65 are thought to be more difficult to treat due to the co-existence of other conditions such as diabetes mellitus, arthritis and renal pathology (Ndimande, 2006) as well as other longstanding chronic diseases. The elderly patient may exhibit elevated systolic and diastolic pressures due to renal and endocrine conditions such as thyrotoxicosis and Paget's disease. Although treatment and management regimes may be the same for elderly patients and younger patients suffering from Hypertension, it must be taken into consideration that the elderly patient may be taking drugs for other pathology co-existing in the body (Ndimande, 2006). In a cross-sectional survey on Complementary and Alternative Medicine use among adults 65 years and older with Hypertension in the United States by Bell, Suerken, Grzywacz, Lang, Quandt and Arcury (2006), it was found that those diagnosed with Hypertension were mainly female with two or more chronic conditions. Many patients over the age of 65 have been diagnosed Hypertensive

years back and are already on conventional treatment. As per the exclusion criteria, a patient would not be included in the study if they were previously on any form of antihypertensive treatment and will not be allowed to participate if they stop current medication in order to join the study. In an observational study by Dulmen, Groot, Koster and Heiligers (2010), patients seeking homeopathic treatment averaged around the age of 39.5 years and one of the most frequent chronic conditions patients seeking complementary medicine suffered from was Hypertension. During a study conducted by Teut, Ludtke, Schnabel, Willich and Witt (2010), on the Homeopathic treatment of elderly patients, nine participants had passed away, therefore it was decided that participants over the age of 65 be excluded from the trial for fear of a high dropout rate due to fatality. Furthermore, the longstanding nature of chronic diseases in elderly patients combined with the short duration of the trial would not yield the desired results as participants would need to be followed up months to years later. It was for these reasons that participants over the age of 65 were excluded from the study.

The incidence of Hypertension was highest in the female Coloured population at 24 percent, followed by the White male population at 23 percent, the female Asian population at 20.3 percent and the African female population at 18.9 percent, the Coloured male population at 15.3 percent, the Asian male population at 14.1 percent and the White female population at 9.9 percent with the African male population having the smallest incidence of 6.9 percent. The male respondents having high blood pressure consisted of 10 percent residing in an urban setting and six percent in a rural setting.

These statistics infer that Hypertension is a serious problem in this country, prompting investigation into treatment, prevention and lowering of potential risks.

## **2.4 PHYSIOLOGICAL REGULATION OF BLOOD PRESSURE**

Blood pressure levels are dependent on the interaction of many genetic, environmental and demographic factors that impact on two haemodynamic variables i.e. cardiac output and total peripheral resistance (Kumar, Cotran and Robbins,

2003). Cardiac output is the volume of blood ejected from the ventricles of the heart to the aorta or the pulmonary trunk every minute.

Blood volume, which is dependent on the body's sodium homeostasis, affects cardiac output. Total peripheral resistance is determined by neural and hormonal influences, vascular tone, autoregulation of the vessels as well as factors such as pH and hypoxia (Kumar *et al.*, 2003).

Homeostasis of blood pressure is also regulated by the kidneys:

Renin secreted by the juxtaglomerula cells of the kidney converts plasma angiotensin into angiotensin I, which in turn is converted into angiotensin II by angiotensin converting enzyme. Angiotensin II directly affects the vascular smooth muscle cells producing vasoconstriction, which increases total peripheral resistance. It also stimulates aldosterone secretion, which causes sodium and fluid retention, leading to an increase in blood volume and a resultant increase in cardiac output. A graphic representation can be found below:

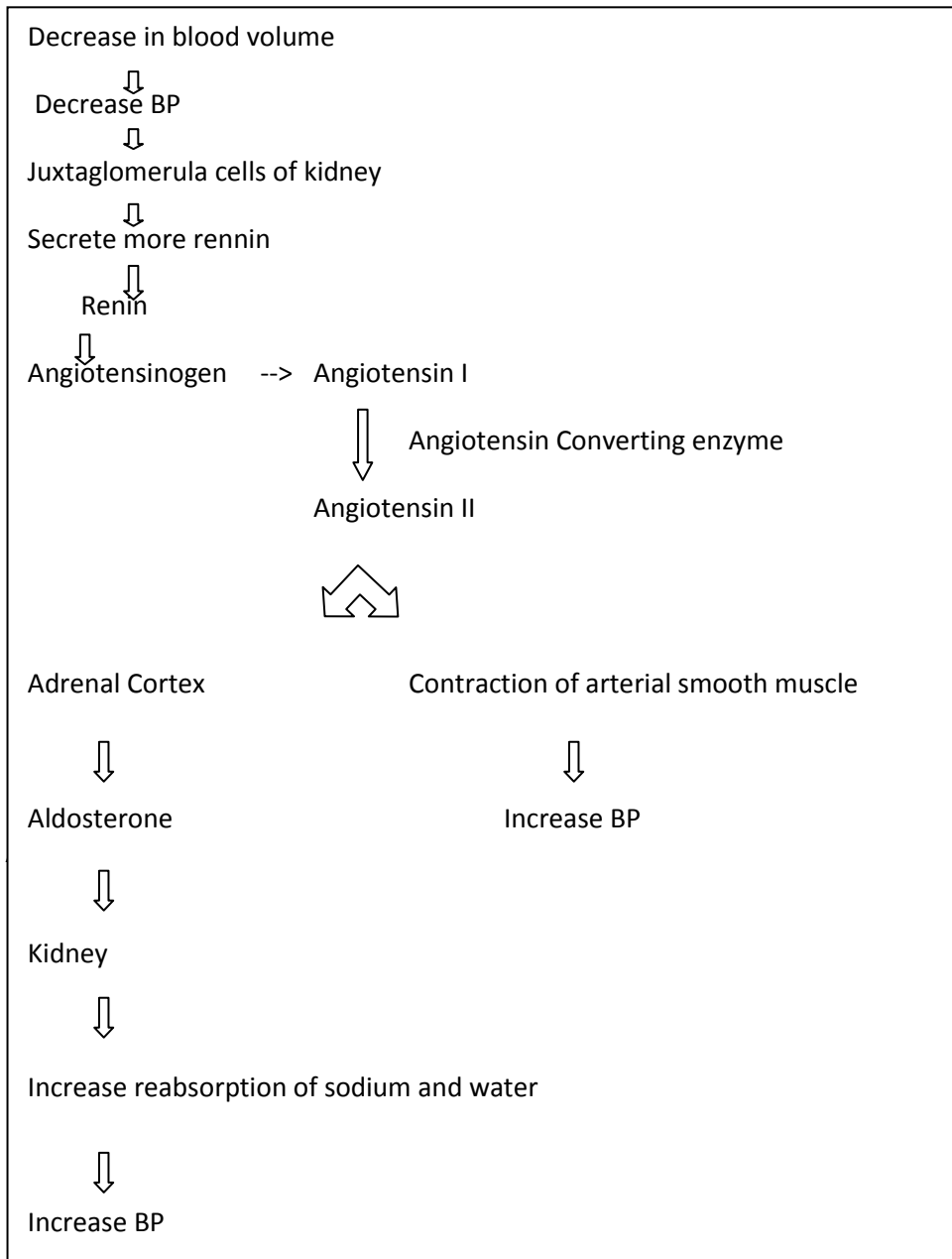


Figure 2.1: Homeostasis of blood pressure by the kidneys

The kidneys also produce antihypertensive substances, such as prostaglandins and nitric oxide, which regulate the blood pressure by counter-balancing the effects of angiotensin. A reduction in blood volume leads to a decrease in the glomerular filtration rate. This prompts for more sodium to be reabsorbed by the tubules, with fluid following, increasing blood volume and thus cardiac output. Atrial natriuretic peptide is secreted by the atria of the heart to inhibit sodium reabsorption by the distal tubules as well as cause vasodilation, in response to elevated blood volume levels (Kumar *et al.*, 2003).

## **2.5 CURRENT TREATMENT**

According to Beers, Porter, Jones, Kaplan and Berkwits (2006), patients should be awarded the opportunity of reducing their blood pressure by non pharmacological methods before commencing pharmacological treatment.

These methods include:

- Weight reduction: this may remove the need for drug therapy for patients whose body mass is ten percent above the norm (18.5kg/m<sup>2</sup> – 24.9kg/m<sup>2</sup>)
- A decrease in alcohol assumption as this has a vasopressor effect and may further increase the blood pressure levels.
- Regular exercise, for patients with a low cardiovascular risk, 30 minutes at a time, three days a week is known to result in a great reduction in blood pressure.
- Dietary changes, such as decreased sodium intake, have been proven effective in reducing blood pressure. It also enhances the efficacy of drugs used in the treatment plan. This may be done by simply reducing table salt intake, which is a common form of sodium. Reduction of the amount of cholesterol and saturated fat consumed would also assist in weight loss.

### **2.5.1 PHARMACOLOGICAL THERAPY**

There are five main classes of antihypertensive described by Beers *et al.* (2006). These are Adrenergic antagonists, Diuretics, Calcium Channel blockers, Renin Angiotensin system inhibitors, and Direct Acting vasodilators.

#### **1. Adrenergic antagonists**

##### **1.1. Beta adrenergic antagonist/Beta Blockers**

These agents inhibit the effects of the catecholamines at beta adrenergic receptors resulting in a decrease in heart rate and cardiac output. They also cause a decrease in plasma renin and plasma volume and initiate a resetting of baroreceptors to acknowledge a lower level of blood pressure, as well as the release of vasodilating prostaglandins. They are also thought to have an effect on the central nervous system to reduce blood pressure. Acute treatment with a Beta Blocker is found not to

be very effective in reducing high arterial pressure due to the compensatory increase in systemic vascular resistance (Klabunde, 2005).

Side effects of these drugs include heart failure, atrioventricular block, Raynaud's phenomenon, impotency, insomnia, depression and nasal congestion. An example of this drug is Propanolol (Beers *et al*, 2006).

## **2. Diuretics**

Diuretics work to decrease blood volume. They also produce slight vasodilation by preventing sodium entry into the cells and promoting its excretion by the kidneys. Combining two diuretics is thought to be more effective than using one alone (Klabunde, 2005). In a case controlled study by Largent, J.A, McEligot, A.J, Ziogas, A, Reid, C, Hess, J, Leighton, N, Peel, D and Anton-Culver, H, (2006), it was found that a history of treated Hypertension with Diuretics was associated with a significant increase in the risk of breast cancer and this appeared in obese women.

Side effects include weakness, muscle cramps, impotency, pancreatitis, electrolyte abnormalities, renal tubular damage and renal calculi. An example of this drug is Hydrochlorothiazide (Beers *et al*, 2006).

## **3. Calcium Channel Blockers**

These agents produce arteriolar vasodilation by blocking the inflow of calcium into vascular smooth muscle. These drugs have only minimal effects on venous capacitance vessels (Klabunde, 2005).

Side effects include nausea, constipation, headaches, orthostatic hypotension, skin rash, flushing, and oedema of the lower limbs. An example of this drug is Nifedipine (Beers *et al*, 2006).

## **4. Renin Angiotensin system inhibitors**

### **4.1 Angiotensin-converting enzyme (ACE) inhibitors:**

These agents inhibit ACE resulting in little or no production of angiotensin II, leading to vasodilation and natriuresis. ACE inhibitors increase bradykinin and some may enhance the production of vasodilatory prostaglandins.

Side effects include angioneurotic edema, hypotension, dry cough, glomerulopathy, a disturbance in taste and leucopenia. It cannot be used in patients with severe renal insufficiency. An example of this drug is Enalapril (Beers *et al*, 2006).

### **4.2 Angiotensin receptor antagonist**

These drugs block the vasoconstrictive effects of angiotensin II at the AT1 receptors resulting in a drop in peripheral vascular resistance.

Side effects include allergic reactions, rash, angioedema, dry cough and hyperkalemia. An example of this drug is Losartan (Beers *et al*, 2006).

## **5. Direct acting vasodilators**

These agents are usually only used to treat pre-eclampsia in pregnancy. They have a direct effect causing vasodilation, but this lowering of blood pressure is short lived due to the drug producing reflex sodium and water retention and increased stimulation of the sympathetic nervous system, producing tachycardia and leading to an increase in blood pressure. For this reason, it cannot be used in patients with ischaemic heart disease. These agents often need to be used in conjunction with diuretics or beta adrenergic antagonists to ameliorate its side effects.

Side effects include nausea, headaches, emesis, tachycardia and postural hypotension (Beers *et al*, 2006).

According to the latest South African Hypertension Guidelines 2006 published in the South African Medical Journal (April 2006), if Hypertension is uncomplicated, it is treated with Diuretics, ACE Inhibitors and Calcium Channel Blockers. Step One

therapy includes the use of low dose thiazide diuretics. Step two and three therapy includes ACE Inhibitors or Calcium Channel Blockers being added to the thiazide diuretics although cost and compelling indications should be considered first. Beta Blockers are not used in Step one, two or three therapy due to their risk of inducing type 2 Diabetes and their ineffectiveness in reducing cardiovascular mortality.

### **2.5.2 HOMOEOPATHIC TREATMENT**

According to Hahnemann, Homoeopathy is a form of medicine based on the principle of '*similia similibus curentur*' i.e. 'like cures like', and whose medicines, in the form of remedies, acts to alter the body's deranged life force, to return it to a normal healthy state. It is when this life force, or vital force becomes deranged that a diseased state results. These remedies are prescribed to the patient in highly dilute doses that is enough to ameliorate the patient's symptoms without any adverse effects (O' Reilly, 2001).

The principle of like cures like is based on a substance eliciting symptoms in a healthy person, and promoting cure in a sick person with the same totality of symptoms (O' Reilly, 2001). Homoeopathy uses the patient's totality of symptoms to prescribe on, regardless of whether there is a causative organism or not. This is important in conditions such as Hypertension where 95 percent of cases have no identifiable cause and the practitioner can only base his management on the patient's symptoms.

The Homoeopathic simillimum is that single remedy whose picture best fits the patient's totality of symptoms. This single remedy is attained by taking the patient's case and noting well the mental, emotional, physical and peculiar symptoms and ranking them in the order of intensity that they present (O' Reilly, 2001:130). Follow up consultations are essential in order to judge whether the remedy prescribed has had an effect or not. If the patient has responded to the remedy, it is advised that the Homoeopath wait before prescribing more medicines in order to let the remedy continue working toward cure. If there has been no change in the patient, then the practitioner may prescribe a different remedy (Vithoukas, 1998).



A Homoeopathic complex is a simultaneous prescription of two or more remedies to treat a particular disease process. This form of prescription entails no individualisation, as many patients suffering from a condition will receive the same medicine. In Homoeopathy, the simillimum prescribing is preferred rather than complex prescribing. In this study, the complex will be made up of *Aurum metallicum*, *Lachesis muta*, *Natrum muriaticum* and *Veratum album* as they all affect the cardiovascular system with symptoms pertaining to the hypertensive disease condition (Vermeulen, 2001). It has been suggested by De Schepper (2005) that patients with moderate pathology be given the medicine at a 6ch potency, one teaspoon, twice or three times a day. Based on this method, the participants receiving the Homoeopathic complex will be required to take a 6ch potency, a quarter of a capful, twice a day.

A trial conducted by Walker (1984), with a group of 100 patients treated with the Homoeopathic simillimum, suggests that Hypertension responds well to treatment using the Homoeopathic simillimum. However, it was also found that polychrest remedies were often utilised. These included *Lycopodium*, *Sulphur*, *Natrum muriaticum*, *Lachesis*, *Phosphorous*, *Sepia* and *Pulsatilla* in order of prominence.

Kohler (2004) used a Homoeopathic complex in the treatment of primary Hypertension in adult males over a six week period, which proved to be effective. The complex was composed of *Crataegus oxycantha*, *Rauwolfia serpentina*, *Lachesis muta*, *Natrummuriaticum* and *Veratrum album*, all in 6ch potency. Recommendations were made that the trial be conducted on females to determine whether there too would be a positive effect. It was also recommended that the trial be carried out over a longer period of time.

In a study carried out by Engelbrecht (2006) found that the Homoeopathic remedy *Viscum album* 1x is successful in treating pre-hypertensive adult males. Recommendations were that the trial be carried out on females, as well as other antihypertensive remedies be combined with *Viscum album* to determine its overall effect.

Liebenguth (2000) conducted a trial on 10 participants, using the Homoeopathic simillimum in the treatment of essential Hypertension in black adult males which

revealed that Homoeopathy can be an effective alternative to the current treatment of Hypertension.

There is thus a need to establish the efficacy of the Homoeopathic simillimum in the treatment of hypertension, as well as comparing it to a Homoeopathic complex.

There have been no other studies comparing the use of the Homoeopathic simillimum and a Homoeopathic complex and only a few studies carried out on either the use of the Homoeopathic simillimum, a Homoeopathic complex or a single, specific remedy. Most studies also limited their population to males, recommending repetition of the study on female participants.

## **2.6 REMEDIES INCLUDED IN THE HYPERTENSIVE COMPLEX**

According to Vermeulen (2001) *Aurum metallicum* is indicated for patients suffering with the following conditions:

- Angina with a sense of a crushing weight under the sternum which is worse for ascending
- Cardiac hypertrophy and arteriosclerosis
- Palpitations that are worse at night, for emotions and anxiety
- Pulse is rapid yet feeble and irregular
- Hypertension and Aortic disease
- Headaches with a feeling of outward pressure and roaring in the head
- The heart feels loose on walking

Jouanny (1984) states that *Aurum metallicum*'s pathogenetic action upon the circulatory system is to cause cardiovascular irritability such as palpitations, Hypertension and cardiomegally as well as the sensation as though the heart has skipped a beat and associated weakness in the epigastrium.

Lilienthal (2006) suggests that *Aurum metallicum* exhibits symptoms such as pure cardiac hypertrophy without dilatation and with increased stroke volume as well as fatty heart and atheroma of the heart and blood vessels.

*Lachesis muta* has been described by Vermeulen (2001) to treat the following symptoms:

- Angina with pain of a burning nature under the sternum and on the left side of the heart
- Palpitations and irregular beats
- Arteriosclerosis
- Weak, intermittent pulse
- Pain and numbness felt in the left arm
- Cramp like pain in the heart and a sensation as though the heart is too large
- Hypertension

According to Jouanny (1984), *Lachesis muta* assists in the treatment of Hypertension, palpitations with precordial constriction and congestive headaches mainly on the left side.

Lilienthal (2006), states that *Lachesis muta* is used in the treatment of Artheromatous conditions of the arteries, and has the sensation that the heart is too large for the chest as well as oppressive pains in the chest.

In a trial conducted by Walker (1984), *Lachesis muta* was found to be one of the remedies frequently prescribed as the simillimum.

*Natrum muriaticum* has been described by Lilienthal (2006) to treat fluttering of the heart with a faint feeling, hypertrophy of the heart and heart diseases causing dropsy. Vermeulen (2001) describes *Natrum muriaticum* as being beneficial for the treatment of the following symptoms:

- Headaches of a congestive, heavy nature which may be throbbing and blinding
- Stitching pains in the chest and a cold sensation in the heart
- Palpitations are present that may shake the whole body
- Pulse is fluttering and intermittent
- Circulation is accelerated on motion
- The heart and chest feels constricted

In a trial conducted by Walker (1984), *Natrum muriaticum* was found to be one of the remedies that featured frequently in the simillimum prescription.

*Veratrum album* has been explained by Vermeulen (2001) as possessing the following clinical features:

- Palpitations with loud respiration that may be visible
- Ailments of the heart from tobacco chewing
- Headache with a sensation of a lump of ice in the vertex, with nausea and vomiting and a pale face
- It is an excellent heart stimulant in Homoeopathic doses

Kohler (2004) used *Veratrum album* as part of a complex of remedies together with *Lachesis muta* and *Natrum muriaticum* in the treatment of Primary Hypertension in the treatment of adult males, which proved to be effective.

## **2.7 RANDOMIZED CONTROLLED TRIALS**

The use of Randomized controlled trials (RCT's) in homeopathy has been to test against placebo and to determine the response to characteristic remedies (Kayne, 2006). In order to test medicines and placebo, evidence based medicine has suggested the use of RCT's which are blinded in fashion, using a group of participants suffering from a similar ailment, that have been randomized into separate treatment and placebo groups (Amaya, 2011). If the medicine given to the treatment group eliminates symptoms significantly higher than the placebo, then the medicine has proved to be effective for that particular ailment. Homeopathy uses the same scientific model of research as conventional medicine does however, there are differences between the two systems and this poses certain problems for homeopathy (Shere, 2006).

Homeopathy is based on individualization, where the treatment is tailor made to suit the individual with the prescription based on symptoms of the disease as well as the patient's mental/emotional state, general symptoms such as sleep and appetite as well as medical history. These factors would not allow for accurate results in a RCT

where one type of medicine is given to all participants regardless of the different nature of each individual (The Evidence for Homeopathy, 2010). In conventional medicine, groups are compared for age, sex, race, social status or occupation whereas human diversity is not taken into account. Homeopathy requires different aspects of the human being to be analyzed in order to compare the patients' symptoms with the drug picture therefore making it impossible to acquire two groups of participant requiring the same remedy (Kayne, 2006). Individualization may only occur if the trial is limited to specific prescription or complexes.

Conventional medicine treats a particular disease entity and its symptoms whereas homeopathy treats the patients' totality of symptoms as a whole, therefore if the research in question is posed against placebo, research protocols remain the same as for conventional medicine. However, this may still advocate errors in the research results as RCT's measure quantitative parameters (Shere, 2006).

The process of randomization and double blinding protects against bias however, if the research design distorts the treatment effect being tested, then the results will not be accurate and the double blinding will not contribute to the understanding of the processes observed (Shere, 2006). Randomization may not always generate groups that are equal in all baseline characteristics. In small studies, baseline differences between groups may occur and a treatment can only be associated with the outcome after all baseline differences have been taken into account (Lewith, Jonas, and Walach, 2011). Furthermore, blinding also poses difficulties when RCT's are applied in homeopathy because the initial consultation requires a full case taking of the participant in order to find the appropriate remedy to start the healing process. However in an RCT, the prescriber is unaware of the group the participant is in so as to avoid bias at the follow up consultations. This blinding prevents the homeopath from acquiring the necessary feedback to make appropriate changes to ensure treatment success (Amaya, 2011).

Another issue arising in RCT's and homeopathy is that each individual's response to the remedy may be different; therefore it is imperative that the research design is uniquely adapted to suit the area of interest. Some participants may exhibit a placebo response, effecting symptoms that fall within the targeted research areas, therefore it is important not to specify the target symptoms ahead of the trial. In

conventional medicine the RCT may be split in two and may be 'crossed over' to control vulnerability of inequalities in the two groups. But cross over designs do not work in homeopathy as the outcomes are specific to the control and not to the participants characteristics (Shere, 2006). Treatment trials on babies and animals would prove to be good evidence that the homeopathic medicine is effective as these subjects cannot verbally express what they feel and are usually not affected by psychosomatic influences (Amaya, 2011).

Clinical trials of homeopathy may be adapted to suit the principles of homeopathy but this may lead to conflict with the conventional research community (Kayne, 2006). The research protocol in this study was designed to ensure that blinded observation produced objective and accurate results. Evidence has been found that the baseline value of the outcome may influence the outcome after treatment. Due to this, Analysis of covariance (ANCOVA) with baseline values as a covariant is suggested as an analytical approach for all RCT's and these accounts for any variances in the baseline values between the groups within the study (Lewith et al., 2011).

## **CONCLUSION**

From the literature obtained in the materia medica, it is evident that Homoeopathy has proven to be effective in the treatment of Hypertension. However in this study, it is of interest to note which remedies are more effective in the treatment of Primary Hypertension.

## **CHAPTER 3**

### **3.1 PARTICIPANTS**

The method of sampling was that of purposive sampling. The onus was upon the researcher to select the participants who will be able to provide adequate information. This type of sampling is said to be ideal for a clinical trial as generalization is not needed but rather the focus is on the population suffering from the disease (Bowling and Ebrahim, 2005).

Participants were recruited through advertisements placed on notice boards at the Durban University of Technology, medical centres, pharmacies, health shops, and libraries.

A minimum of 30 participants were recruited and were selected on the basis of specified inclusion and exclusion criteria set out below, and randomly divided into two equal groups by the research supervisor, with the first group receiving the Homoeopathic simillimum and the second group receiving the Homoeopathic complex. This ensured double blinding to eliminate research bias.

Inclusion criteria were:

- Females between the ages of 18 and 65
- Participants conforming with the diagnostic criteria for hypertension as defined by the JNC VII (Chobanian *et al*, 2003) as discussed in the literature review under section 2.1
- Or already being diagnosed by a Primary Health Care Provider, General Practitioner or Physician.

Exclusion criteria were:

- Breastfeeding or pregnant women
- Individuals younger than 18 or older than 65
- Malignant hypertension
- Hypertension above 190mmHg systolic and 120mmHg diastolic

- Participants currently on any medication that would have an effect on the blood pressure. This study will disallow the participation of patients who discontinue their current medication in order to join the study.
- Participants with renal or endocrine disease.
- Participants with a history of Cardiac surgery.

All participants received an information guide and consent form (Appendix F), providing details about the trial, which was signed by the participant.

### **3.2 TRIAL PROCEDURE**

Participants that met the criteria were scheduled for an appointment with the researcher. This initial consultation took place at the Durban University of Technology or at the Umlazi Medical Centre and the participant was asked to sign the informed consent form (Appendix D). Selected participants were randomly assigned by the supervisor into either the Homoeopathic Simillimum group or the Homoeopathic Complex group.

A detailed case history was taken, followed by a complete physical examination including blood pressure readings and cardiovascular system examinations. The researcher discussed the choice of remedy, dosage and potency with a clinician. Dosage was decided upon following Hahnemann's (O'Reily, 2001:251) advice that the dosage should be determined by experiment, observing the excitability of the patient and the correct experience. Potency was decided upon according to De Schepper's (2007:68-79) theory that a hypersensitive patient should receive a lower potency, a normosensitive patient should receive an intermediate potency and a hyposensitive patient should receive a higher potency. The sensitivity of the patient is based upon the strength of his vital force with a hypersensitive patient having a weak vital force and a hyposensitive patient having a strong vital force. The prescription was dispensed according to the randomization sheet formulated by the supervisor.

Follow up consultations occurred every week for a period of four weeks to record blood pressure readings, any changes in the general health and well being of the participants, and to prescribe more medicines if needed, all of which was recorded.



A mercury sphygmomanometer and a Littmann Classic 2 stethoscope were the tools of measurement and was used according to the method outlined by Bickley and Szilagyi (2007), which states that an accurate measurement of blood pressure is dependent on the appropriate cuff size of the sphygmomanometer and whether the type of gauge used needs to be calibrated or not. Aneroid gauges need to be calibrated regularly, whereas mercury gauges would provide more accurate readings, irrespective of calibration.

The following steps as outlined by Bickley, L.S, and Szilagyi, P.G,(2007) were adhered to in order to obtain accurate, reliable measurements:

- The patients did not smoke or consume caffeinated drinks thirty minutes before the measurement.
- The room was quiet and at a comfortable temperature.
- The patient was seated for five minutes with feet on the floor and the arm at heart level.
- The arm was clothing free and did not have any signs lymphodema, fistula's or scarring from possible brachial artery cut downs.
- The brachial artery was palpated, to note that it had a pulse.

Once these steps were followed, the cuff was placed over the brachial artery, with the lower border 2.5cm above the antecubital crease. The patients arm was relaxed, and slightly flexed at the elbow.

Thereafter, systolic pressures were measured by palpation of the radial artery and the cuff inflated until the radial pulse disappeared. The pressure at which the radial pulse disappeared was noted and 30mmHg added to this.

The cuff was deflated completely and a period of thirty seconds was allowed to lapse.

Following this the bell of the stethoscope was placed over the brachial artery, making sure that it was sealed all round. The cuff was rapidly inflated to the figure obtained, and slowly deflated the cuff at about 2mmHg per second.

Systolic pressure was obtained when two consecutive beats were first heard. These sounds are known as Korotkoff sounds.

The cuff was allowed to continue deflating until the sounds become muffled and disappeared. At this point diastolic pressure was noted.

The study was double blind in that neither the researcher nor the participants knew which group they have been assigned to. Only the supervisor was aware as to which participant was in which group.

The table below depicts the distribution of groups and the relevant control methods.

	<b>Simillimum prescription</b>	<b>Complex prescription</b>
<b>Group 1: Simillimum group</b>	Verum/Active Remedy	Placebo
<b>Group 2: Complex group</b>	Placebo	Verum/Active Remedy

Table 3.1: Prescription methods of various groups

Participants in the Homoeopathic simillimum group received verum simillimum and placebo Homoeopathic complex. Those in the Homoeopathic complex group received placebo Homoeopathic simillimum and verum Homoeopathic complex. This was done by prescribing one bottle of liquid, an envelope of powders and a vial of granules that was either placebo or remedy, depending on which group the participant belonged to in order to maintain the blinding of the trial by dispensing medicines that all appeared to be the same.

### **3.3 REMEDY PREPARATION**

Participants being treated with simillimum received either active drops or powders, depending on the potency chosen. This was done so that the participant received the preferred simillimum dosage form whilst still maintaining the blinding of the trial. The other dosage forms were placebo.

#### **3.3.1 SIMILLIMUM PREPARATION**

If the participant was in the simillimum group and the dosage form chosen were powders, then the prefolded powders containing five hundred milligrams of lactose powder were utilised and the remedy was sourced, in its required potency, from the DUT dispensary and impregnated into the lactose powders by means of 10 triple impregnated lactose granules. A range of potencies was used so that each

participant received their preferred simillimum in a dose suitable particularly to that individual in order to obtain more beneficial results. Ascending potencies were prescribed so as to continually stimulate to participants vital force to start the healing process.

If the participant was in the simillimum group and the dosage form chosen was in a liquid then the drops were a plussed potency. The plussed potency was made according to Method 8 of the GHP (Benyunes, 2005) where ten impregnated granules were added to a 25ml dropper bottle followed by 18mls of purified water. The bottle was then swirled to dissolve the granules and once completely dissolved 2,5mls of 96 percent alcohol was added. The bottle was then sealed and succussed ten times and fixed with a label with the appropriate instructions. Administering a plussed potency is thought to have a greater influence on the patient by dynamically penetrating throughout the body rapidly because the action of succession causes the medicine itself to become more powerful in potency (Dudgeon and Boericke, 2001). In the 5<sup>th</sup> edition of the Organon, Hahnenamm concludes that if the remedy is administered in liquid form then the greater its medicinal power. Furthermore if the remedy is succussed, it provides a deeper more rapid penetration of the vital force to start the healing process by increasing its potency (Dudgeon and Boericke, 2001). Slightly altering the potency with each succussion prevents any aggravation from administering the same potency repeatedly. When the medicine needs to be repeated more frequently, such as in chronic diseases, it is best to give it in a liquid form and where the bottle is succussed before each dose to alter the potency so as to gently stimulate the vital force (Tafel, 1997).

If the LM potency scale was required, then it was made up according to Method 17 of the GHP (Benyunes, 2005), where one impregnated granule is added to a 25ml dropper bottle, followed by 15mls of purified water and dissolved by swirling the bottle. Thereafter 5mls of 96 percent alcohol and the bottle is sealed and labelled with the appropriate instructions.

Participants in this group also received a No.3 vial containing unmedicated neutral granules as a control.

Classical homeopathy prefers the use of single remedies as their actions have been proven on healthy human beings whereas complexes of remedies have not been

proven hence we are unable to predict the action upon the body. Administering one remedy at a time allows the homeopath to distinguish between the actions of individual remedies on the body as well prevents confusion or disharmony within the vital force (de Schepper, 2007).

### **3.3.2 COMPLEX PREPARATION**

Participants in the Homoeopathic complex group received a No. 3 vial of active granules containing the complex of remedies, one bottle of placebo liquid (only containing 18mls of purified water and 2,5mls of 96 percent alcohol) and an envelope of placebo powders (impregnated with 10 neutral lactose granules as a control).

The Homoeopathic Hypertensive complex was prepared by CoMed Health Pty Ltd according to Method 10 of the German Homeopathic Pharmacopoeia (Benyunes, 2005).

*Aurum metallicum* 6cH is produced by Method six of the German Homeopathic Pharmacopoeia (Benyunes, 2005). This method involves triturating the one part of the raw material with 99 parts of lactose monohydrate as the vehicle. The vehicle is divided into three parts and the first part is triturated alone. Then the raw material is added and triturated further, followed by the second part which is further triturated. The same is done with the third part. This process needs to be carried out for no less than one hour (Benyunes, 2005). This produced a 1cH trituration. It is then repeated to produce the 2cH and 3cH triturations.

Following this, Method 8a is used to prepare the mixture into a liquid. One part of the 3cH trituration is dissolved in 99 parts of purified water. This is then succussed. One part of this solution is added to 99 parts of 30 percent alcohol and succussed to produce a 5cH potency. The medicines may be co-potentised at an earlier stage according to method 40b of the GHP (Benyunes, 2005), that is before reaching the 6cH stage, to combine all the required remedies at the same level to produce a mixture of all remedies at a 6cH potency in one bottle.

*Lachesis muta* is prepared by triturating 0.3 parts of the dried venom in 99.7 parts of lactose monohydrate. Thereafter Method 6 and Method 8a is used to prepare the 6cH potency as explained above.

*Natrum muriaticum* 6cH is produced by Method 6 and Method 8a of the GHP (Benyunes, 2005) as explained above.

*Veratrum album* 6cH is produced by Method 6 and Method 8a of the GHP (Benyunes, 2005) as explained above.

The Homoeopathic complex was in the form of granules which is made according to Method 10 of the GHP (Benyunes, 2005). This involves triple impregnation at one percent volume/volume of lactose granules by the mixture of *Aurum metallicum* 6cH, *Lachesis muta* 6cH, *Natrum muriaticum* 6cH and *Veratrum album* 6cH in equal parts prior to impregnation and allowing the granules to air dry between each impregnation.

All powders, bottles and vials of medicine were identical and labelled with the same instructions. Powders were labelled with instructions to be taken once daily. Bottles were labelled instructing the patient to take 10 drops twice a day and vials were labelled instructing the patient to take 10 granules three times a day.

All participants received the same number of powders, bottles and vials.

Although classical homeopathy prefers the use of a single, most appropriate remedy, clinical experiences suggests that several remedies can be combined and administered as a complex. Complexes usually contain remedies of the same potency and are directed at the treatment of a particular disease or ailment. In this study, the complex was used as it would provide for a convenient and timely prescription in the public sector if it produced good results. Complexes may also be used if the simillimum remedy cannot be attained because one is not sure of which remedy is most appropriate or when there is a need to treat more than one ailment at the same time (Kayne, 2006).

### **3.4 STATISTICAL ANALYSIS**

Blood pressure readings were recorded every week for a period of four weeks. All blood pressure readings were captured using Microsoft Office Excel 2007 on a spreadsheet. Thereafter the results were analysed and compared using ANOVA tests in SPSS version 18.0. ANOVA is a statistical procedure using the *F*-ratio to test the fit of a linear model and is therefore a test of whether each of the group means differ from each other (Field, 2009). A p value <0.05 was considered as statistically significant. Repeated measures ANOVA tests were done to compare the blood pressures over time between the treatment groups. Specific remedies used at each time point were described by treatment group. Potencies of the remedies were compared within each remedy between the treatment groups using Pearson's chi square tests.

## **CHAPTER 4**

### **RESULTS**

This chapter contains the results obtained from the statistical analysis of the data collected from the two groups used in this trial.

#### **4.1 DEMOGRAPHIC DATA**

##### **4.1.1 AGE**

The study consisted of participants between 18 and 65 years of age. There were two participants (6.7%) between 18-30 years old and six participants (20%) between the ages of 31-40 years. Ten participants (33.3%) were between 41-50 years of age and 12 participants (40%) were between 51-65 years of age.

Figure of graphical representation of age distribution

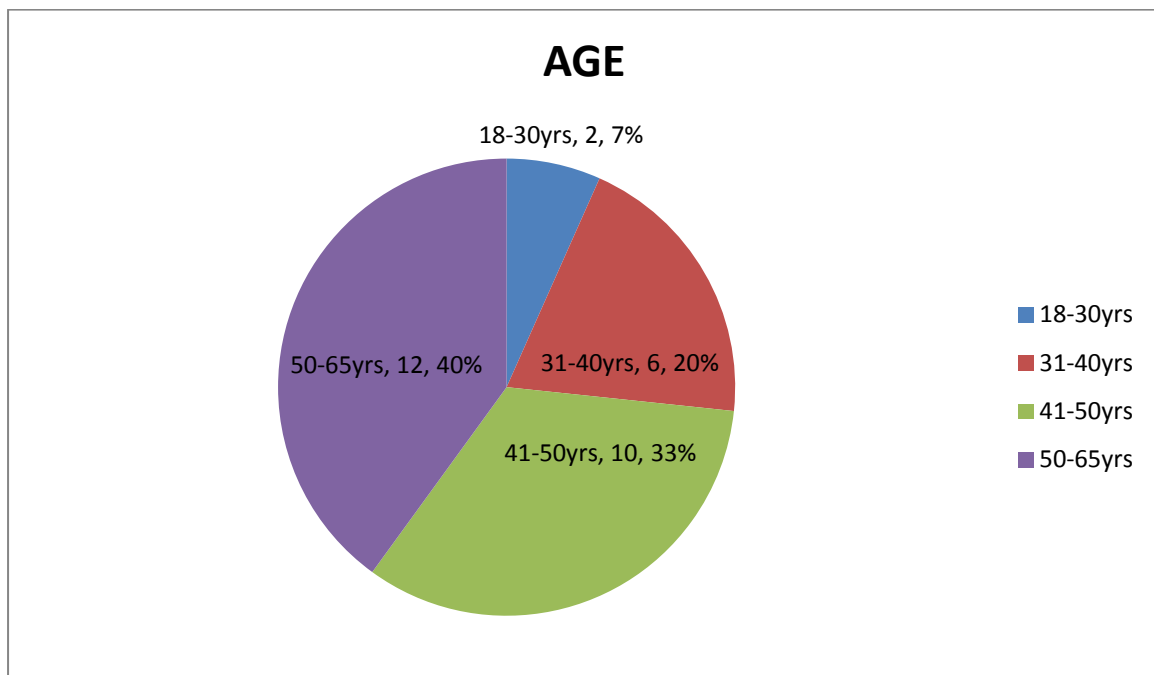


Figure 4.1. Graphical representation of age groups

##### **4.1.2 RACE**

The study consisted of 12 (40%) African participants and 18 (60%) Asian participants. The use of these population groups is attributed to the placement of the clinics as both were situated in areas mainly populated by the African and Asian

communities. Participants were selected randomly as long as they fitted into the inclusion and exclusion criteria,

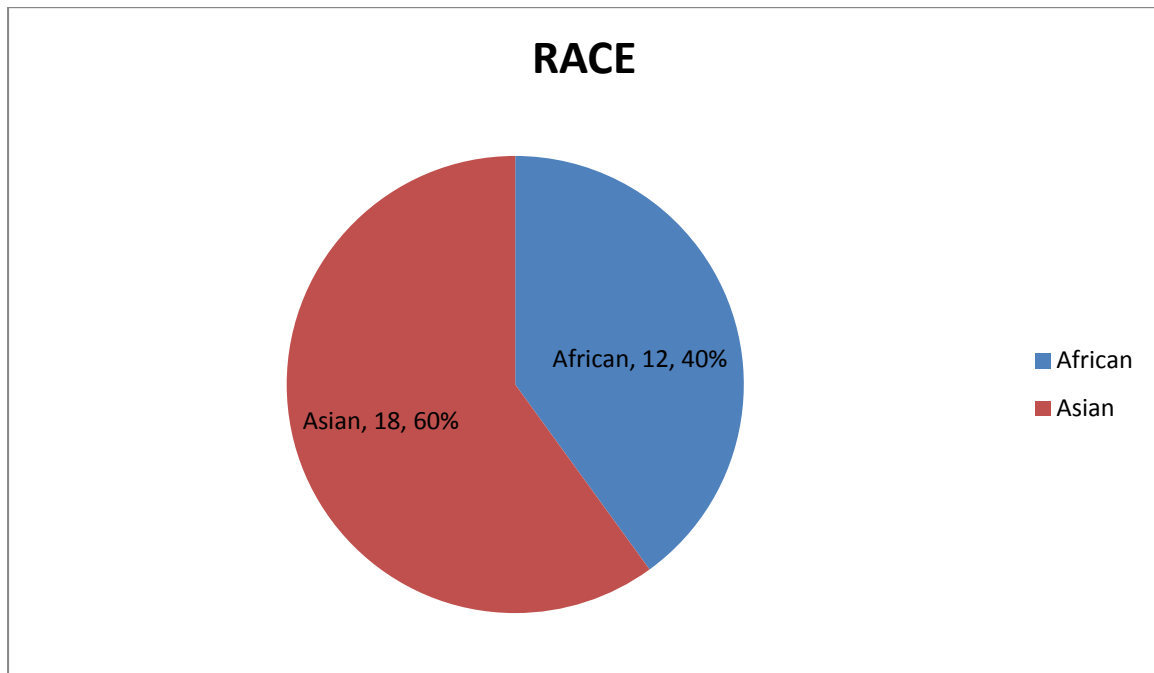


Figure 4.2 Graphical representation of race groups

#### **4.2 HOMOEOPATHIC REMEDIES PRESCRIBED**

Thirty three Homoeopathic remedies were prescribed during the study. Figure 4.3 illustrates the percentage of remedies prescribed for both the simillimum and complex groups. The most predominant remedies were *Natrum muriaticum*, *Sepia officinalis*, and *Pulsatilla praetensis*.



## Percentage of remedies prescribed for both simillimim and complex groups

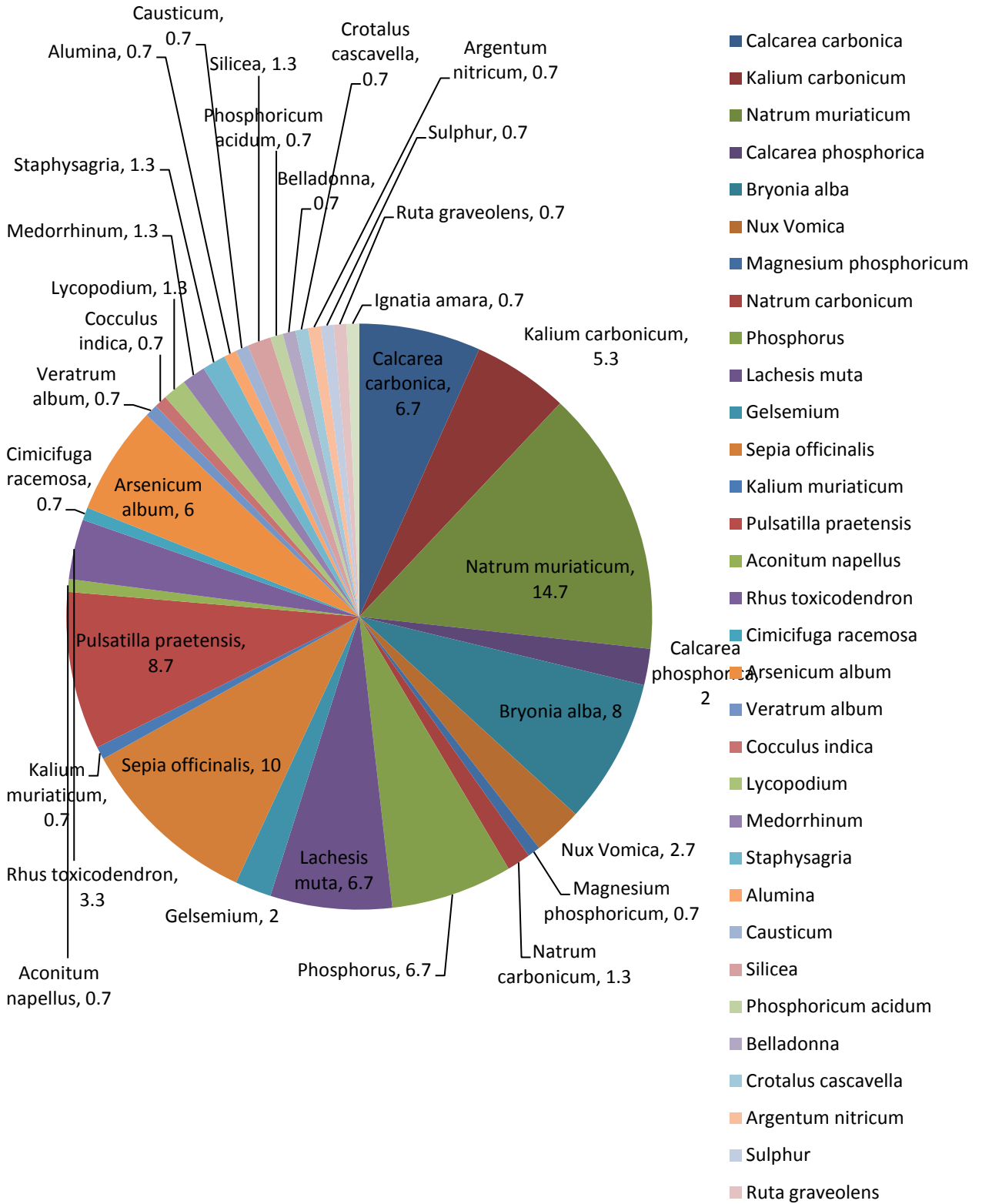


Figure 4.3. Percentage of remedies prescribed in the study (both groups)

There were 25 remedies prescribed and dispensed in the simillimum group, predominantly *Sepia officinalis*, *Pulsatilla praetensis*, *Calcarea carbonica*, *Bryonia alba* and *Natrum muriaticum*. Figure 4.4 illustrates the percentage of the various remedies presented in this group.

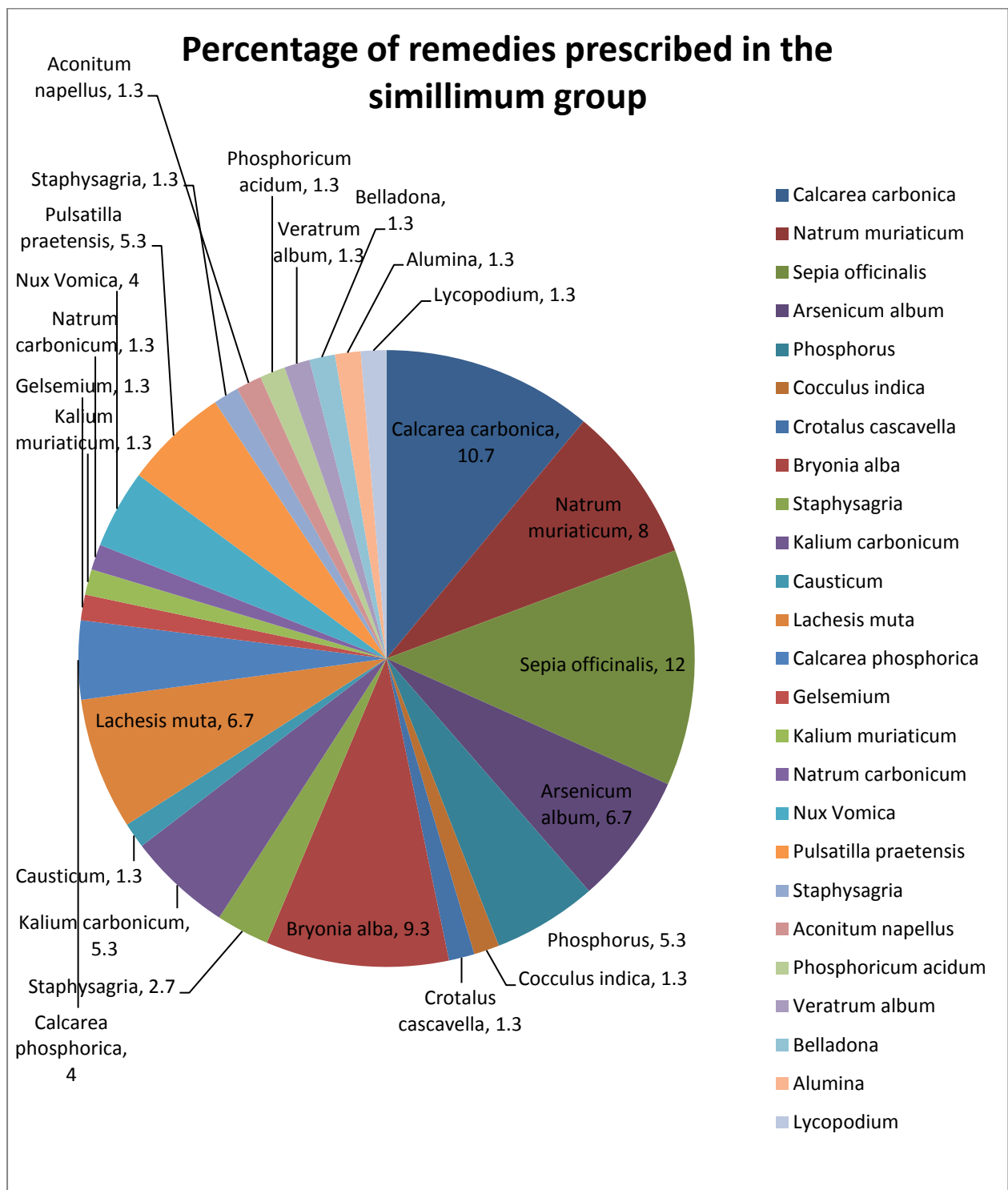


Figure 4.4 Percentage of remedies prescribed in the simillimum group

There were 20 remedies prescribed but not dispensed to the participants in the complex group. These were predominantly *Natrum muriaticum*, *Pulsatilla praetensis*, *Sepia officinalis*, and *Phosphorus*

Figure 4.5 illustrates the percentage of remedies prescribed in the complex group.

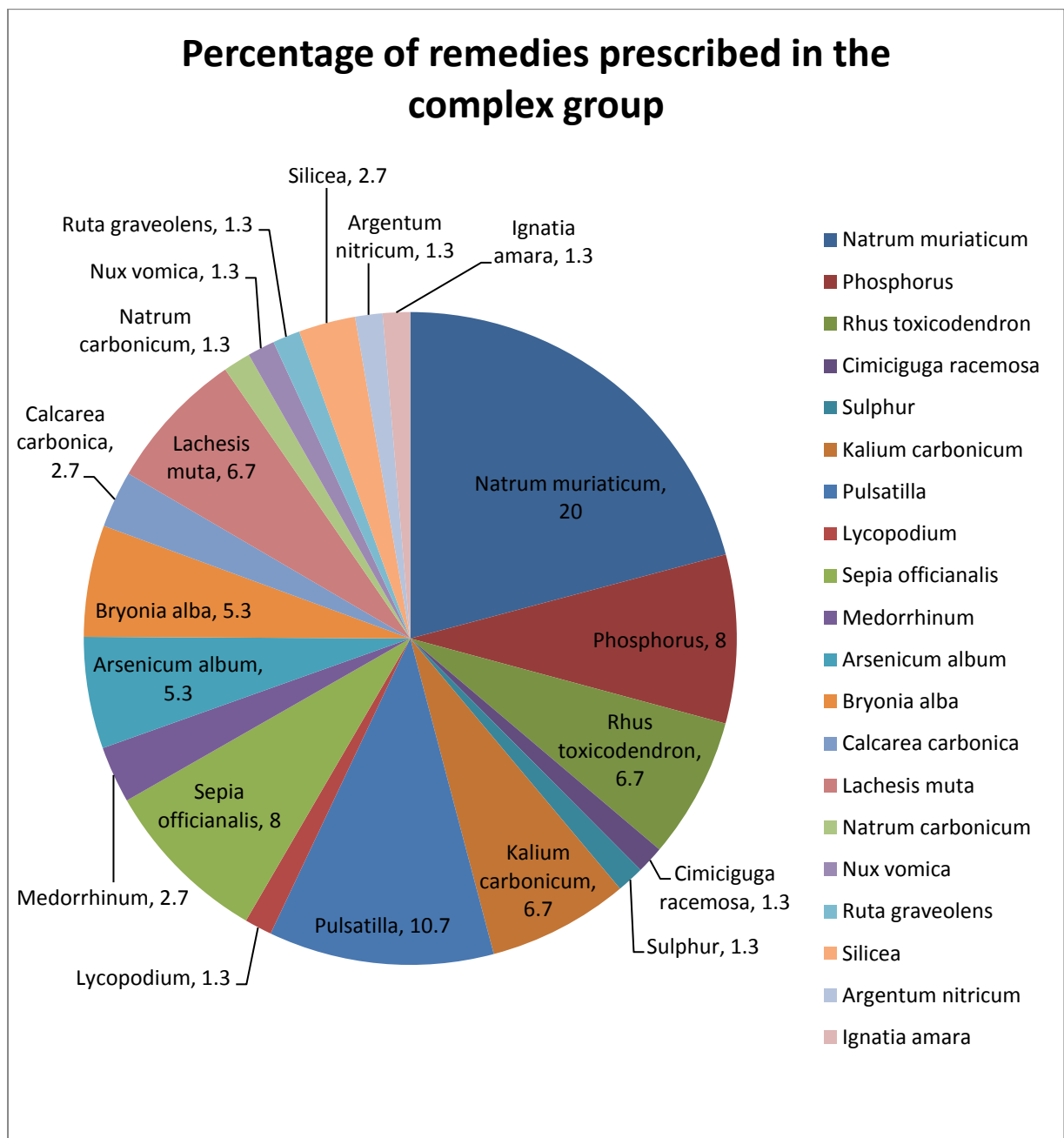


Figure 4.5. Percentage of remedies prescribed in the complex group

### **4.3 HOMOEOPATHIC POTENCIES PRESCRIBED**

The various remedies were prescribed at different potencies ranging from 30cH, 200cH, 1M or 30 plussed. Most patients were prescribed ascending potencies: three powders of 30cH, two powders of 200cH and one powder of 1M.

Table 4.1 represents the remedies and their corresponding potencies prescribed in the study.

<b>Remedy</b>	<b>Potency</b>	<b>Simillimum Group no. Prescribed</b>	<b>Complex Group no. Prescribed</b>
Calcarea carbonica	30cH	18	3
	200cH	12	2
	M	9	4
	30++	1	
Kalium carbonicum	30cH	12	9
	200cH	8	6
	M	4	7
	30++	1	
Natrum muriaticum	30cH	12	18
	200cH	8	12
	M	7	27
Calcarea phosphorica	30cH	6	
	200cH	4	
	M	5	
Bryonia alba	30cH	12	20
	200cH	8	4
	M	12	2
Nux Vomica	30cH	6	3
	200cH	4	2
	M	3	1
Magnesium phosphoricum	30cH	7	
Natrum carbonicum	30cH	3	3
	200cH	2	2
	M	1	1
Phosphorus	30cH	9	12
	200cH	6	8
	M	4	7
Lachesis muta	30cH	12	12
	200cH	8	8
	M	7	7

Gelsemium	30cH	3	6
	200cH	2	4
	M	1	2
Sepia	30cH	18	9
	200cH	12	6
	M	11	12
Kalium muriaticum	30cH	3	
	200cH	2	
	M	1	
Pulsatilla	30cH	6	12
	200cH	4	8
	M	6	14
	30++		1
Aconitum napellus	30cH	3	
	200cH	2	
Rhus toxicodendron	30cH		3
	200cH		2
	M		6
Cimicifuga racemosa	30cH		3
	200cH		2
	M		1
Arsenicum album	30cH	6	6
	200cH	4	4
	M	9	6
Veratrum album	30cH	3	
	200cH	2	
	M	1	
Cocculus indica	30cH	3	
	200cH	2	
	M	1	
Lycopodium	30cH	3	3
	200cH	2	2
	M	1	1
Medorrhinum	30cH		3
	200cH		2
	M		4
Staphysagria	30cH	3	
	200cH	2	
	M	4	
Alumina	30cH	3	
	200cH	2	
	M	1	
Causticum	30cH	3	
	200cH	2	
	M	1	

Silicea	30cH		3
	200cH		2
	M		2
Phosphoricum acidum	30cH	3	
	200cH	2	
	M	1	
Belladonna	30cH	3	
	200cH	2	
	M	1	
Crotalus cascavella	30cH	3	
	200cH	2	
	M	1	
Argentum nitricum	30cH		3
	200cH		2
	M		1
Sulphur	30cH		3
	200cH		2
	M		1
Ruta graveolens	30cH		7
Ignatia amara	30cH		3
	200cH		2
	M		1

Table 4.1 Remedies and potencies prescribed

Figure 4.6 illustrates the number and percentage of potencies prescribed in the simillimum group, and as stated above, most patients were prescribed ascending potencies.

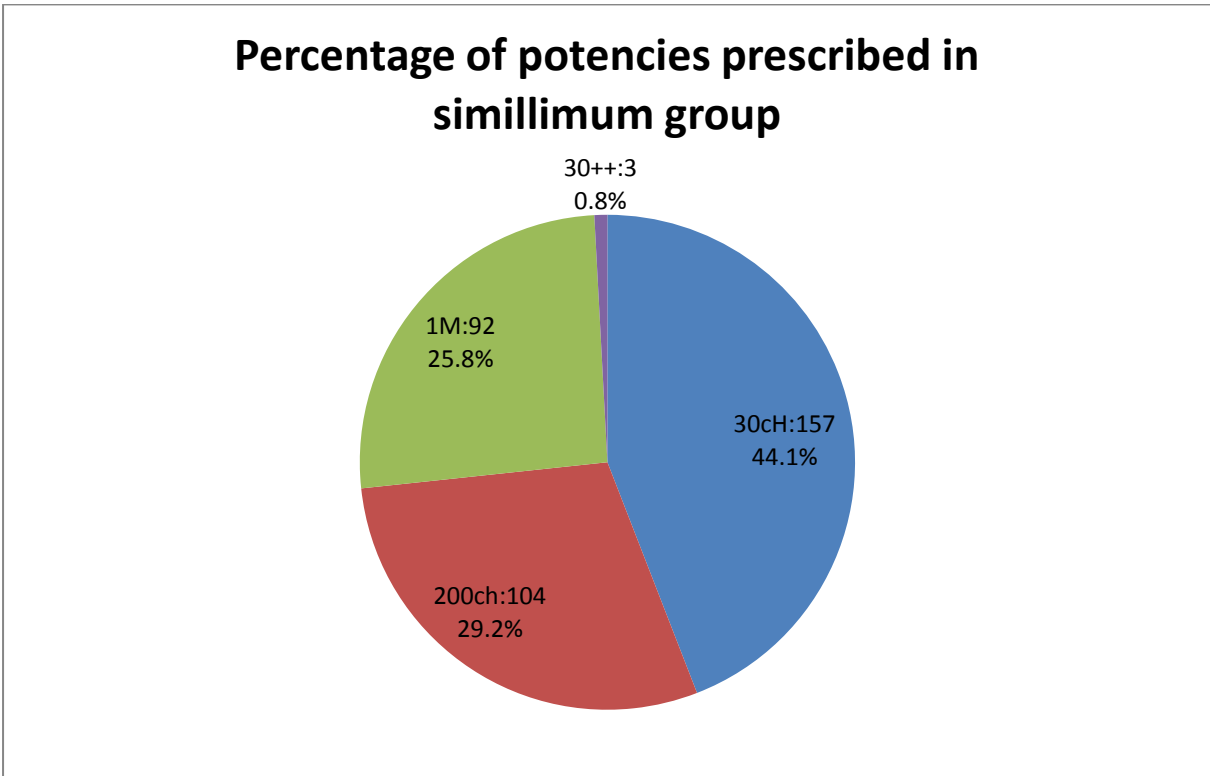
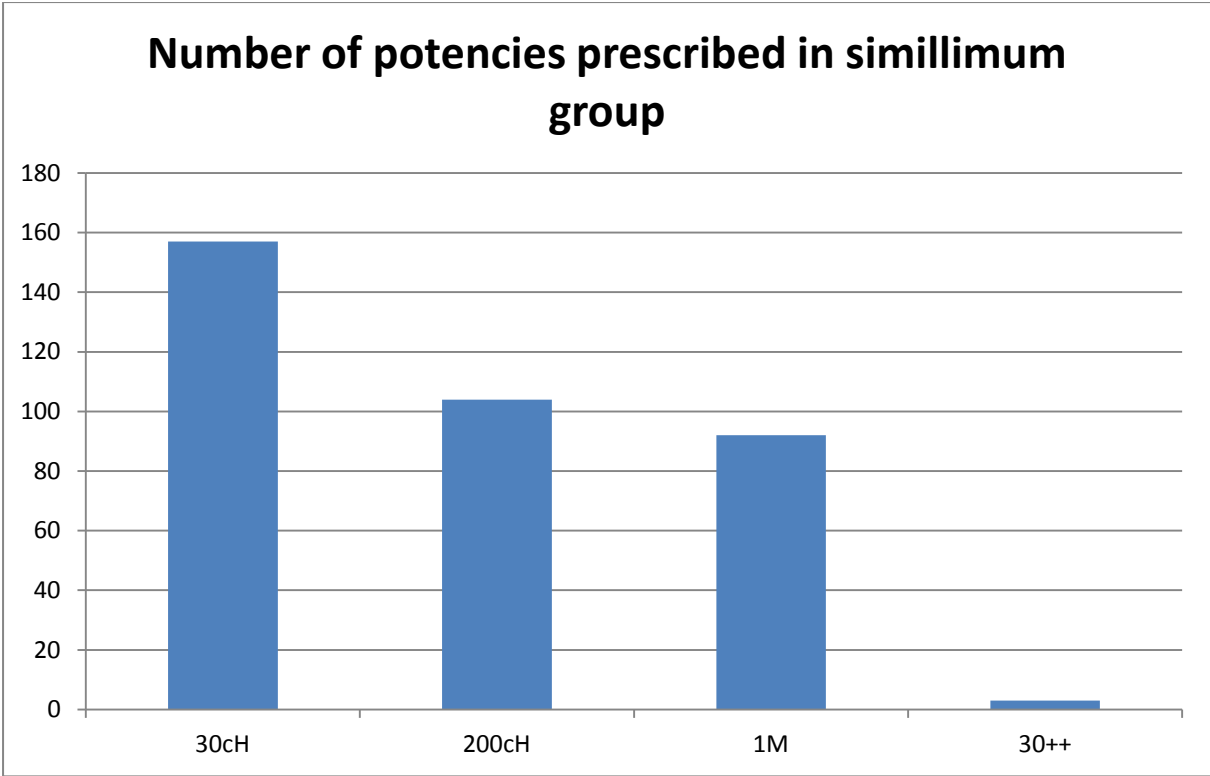


Figure 4.6. Number and percentage of potencies prescribed in the simillimum group

Figure 4.7 illustrates the number of potencies prescribed in the complex group and these were predominantly ascending potencies.

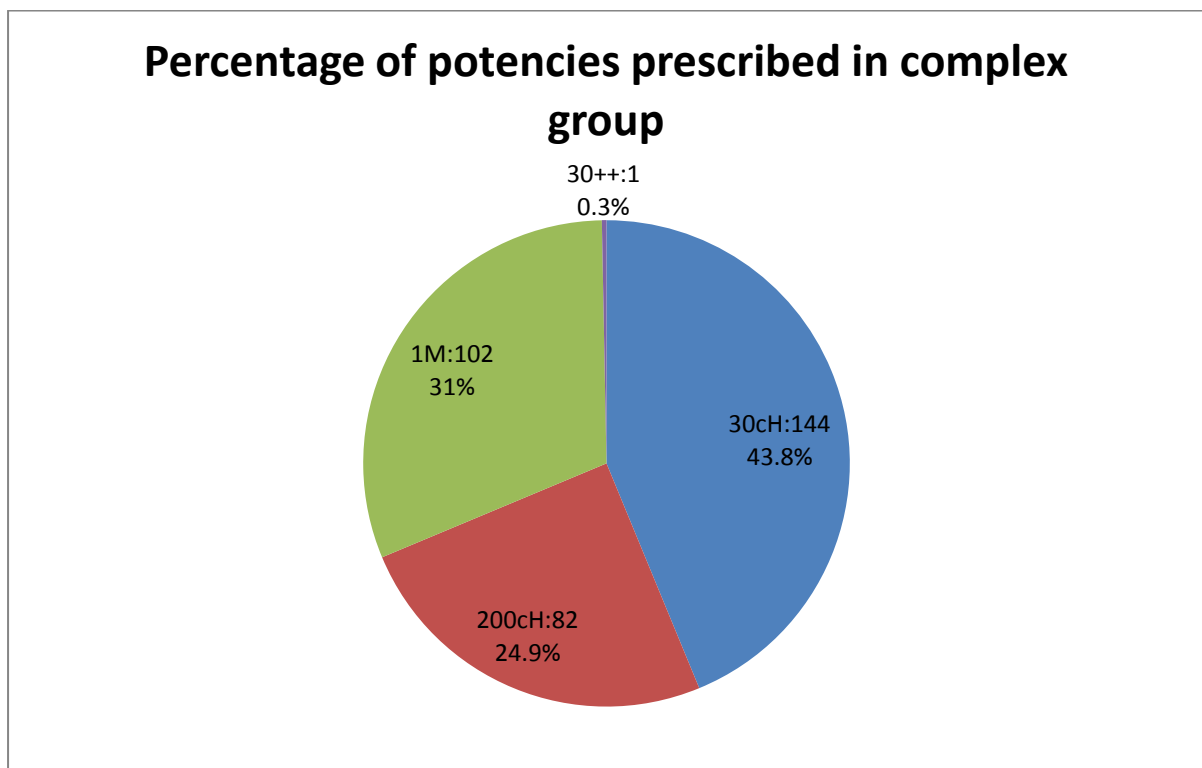
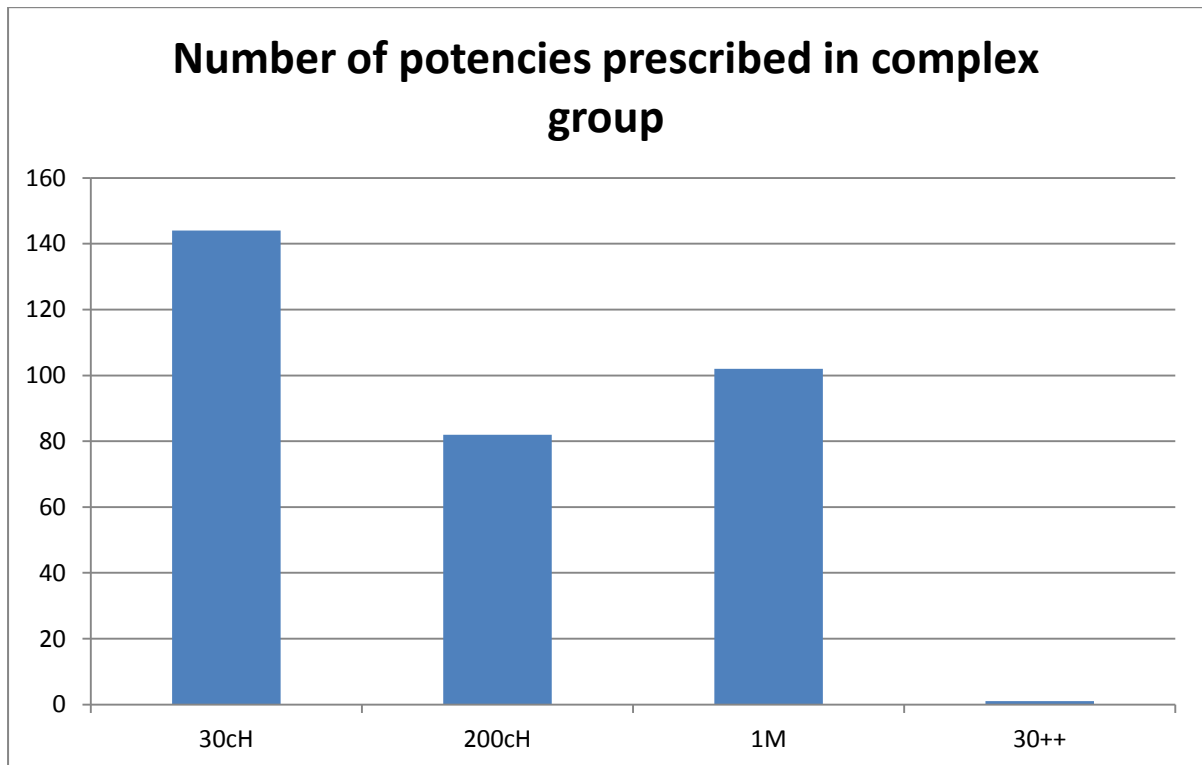


Figure 4.7. Number of potencies prescribed in the complex group



#### **4.4 INTRA-GROUP ANALYSIS**

##### Hypothesis 1

H0: The Homoeopathic simillimum does not lower blood pressure in females that are not currently on any form of treatment.

H1: The Homoeopathic simillimum lowers blood pressure in females that are not currently on any form of treatment.

##### Hypothesis 2

H0: The Homoeopathic complex does not lower blood pressure in females that are not currently on any form of treatment.

H1: The Homoeopathic complex lowers blood pressure in females that are not currently on any form of treatment.

#### **Systolic blood pressure:**

Within each of the two treatment groups there was a highly significant decrease in systolic blood pressure over time ( $p < 0.001$ ). This means that both treatments were effective at lowering systolic blood pressure.

**Table 4.2: Within-subjects effects of time on systolic blood pressure in both treatment groups separately**

Multivariate Tests <sup>b</sup>							
Group	Effect		Value	F	Hypothesis df	Error df	Sig.
Simillimum	time	Pillai's Trace	.901	25.166 <sup>a</sup>	4.000	11.000	.000
		Wilks' Lambda	.099	25.166 <sup>a</sup>	4.000	11.000	.000
		Hotelling's Trace	9.151	25.166 <sup>a</sup>	4.000	11.000	.000
		Roy's Largest Root	9.151	25.166 <sup>a</sup>	4.000	11.000	.000
Complex	time	Pillai's Trace	.864	17.426 <sup>a</sup>	4.000	11.000	.000
		Wilks' Lambda	.136	17.426 <sup>a</sup>	4.000	11.000	.000
		Hotelling's Trace	6.337	17.426 <sup>a</sup>	4.000	11.000	.000
		Roy's Largest Root	6.337	17.426 <sup>a</sup>	4.000	11.000	.000

a. Exact statistic

**Multivariate Tests<sup>b</sup>**

Group	Effect		Value	F	Hypothesis df	Error df	Sig.
Simillimum	time	Pillai's Trace	.901	25.166 <sup>a</sup>	4.000	11.000	.000
		Wilks' Lambda	.099	25.166 <sup>a</sup>	4.000	11.000	.000
		Hotelling's Trace	9.151	25.166 <sup>a</sup>	4.000	11.000	.000
		Roy's Largest Root	9.151	25.166 <sup>a</sup>	4.000	11.000	.000
Complex	time	Pillai's Trace	.864	17.426 <sup>a</sup>	4.000	11.000	.000
		Wilks' Lambda	.136	17.426 <sup>a</sup>	4.000	11.000	.000
		Hotelling's Trace	6.337	17.426 <sup>a</sup>	4.000	11.000	.000
		Roy's Largest Root	6.337	17.426 <sup>a</sup>	4.000	11.000	.000

a. Exact statistic

b. Design: Intercept

Within Subjects Design: time

**Diastolic blood pressure:**

Within each of the two treatment groups there was a highly significant decrease in diastolic blood pressure over time ( $p=0.001$  and  $p<0.001$  respectively). This means that both treatments were effective at lowering diastolic blood pressure.

**Table 4.3: Within-subjects effects of time on diastolic blood pressure in both treatment groups separately**

**Multivariate Tests<sup>b</sup>**

Group	Effect		Value	F	Hypothesis df	Error df	Sig.
Simillimum	time	Pillai's Trace	.804	11.248 <sup>a</sup>	4.000	11.000	.001
		Wilks' Lambda	.196	11.248 <sup>a</sup>	4.000	11.000	.001
		Hotelling's Trace	4.090	11.248 <sup>a</sup>	4.000	11.000	.001
		Roy's Largest Root	4.090	11.248 <sup>a</sup>	4.000	11.000	.001
Complex	time	Pillai's Trace	.876	19.515 <sup>a</sup>	4.000	11.000	.000
		Wilks' Lambda	.124	19.515 <sup>a</sup>	4.000	11.000	.000
		Hotelling's Trace	7.096	19.515 <sup>a</sup>	4.000	11.000	.000
		Roy's Largest Root	7.096	19.515 <sup>a</sup>	4.000	11.000	.000

a. Exact statistic

b. Design: Intercept

Within Subjects Design: time

From the data above, the following is thus evident:

1. The Homoeopathic simillimum resulted in the lowering of both the systolic and diastolic blood pressures, evident in the significant decrease observable. This thus leads to the acceptance of the first hypothesis.
2. The Homoeopathic complex resulted in the lowering of both the systolic and diastolic blood pressures, evident in the significant decrease observable. This thus leads to the acceptance of the second hypothesis

#### **4.5 INTER-GROUP ANALYSIS**

##### Hypothesis 3

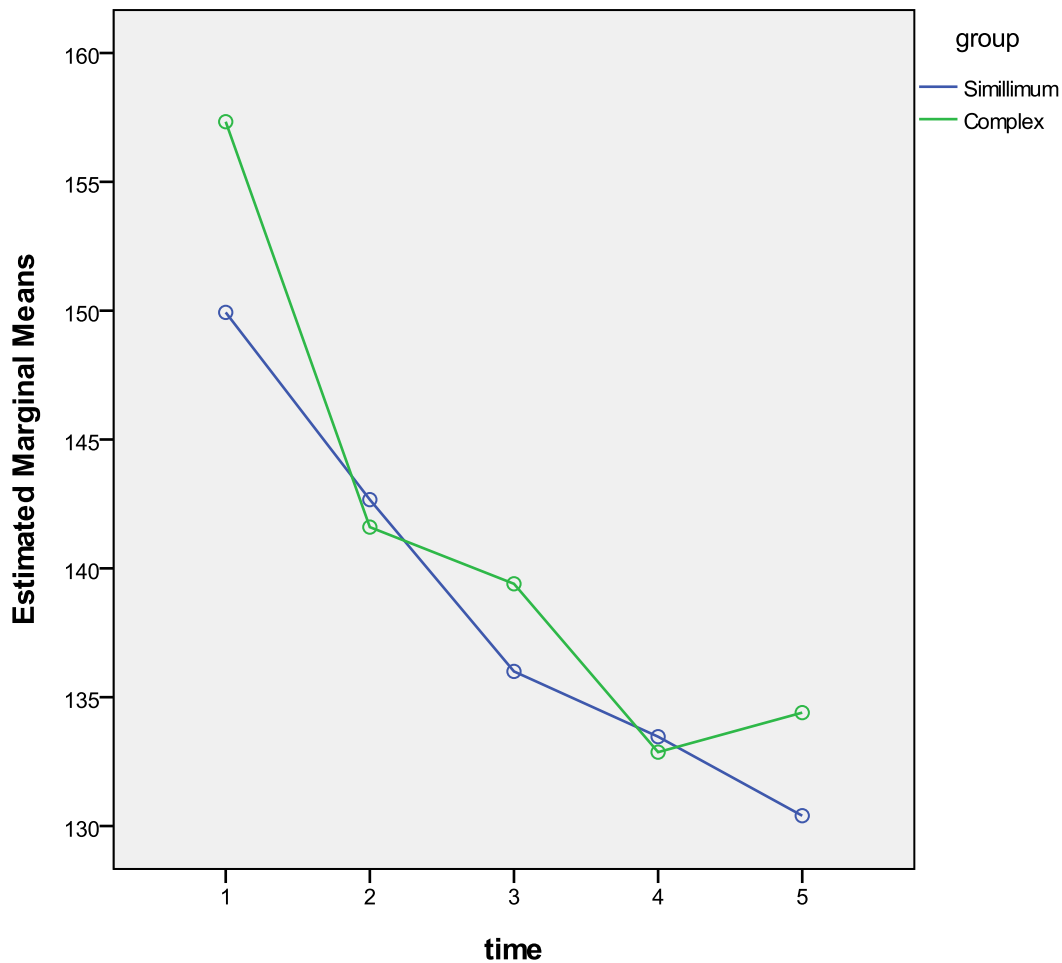
H0: There is no significant difference in the treatment effect between the simillimum and complex groups

H1: There is a significant difference between the treatment effects of the simillimum and complex groups.

Systolic and diastolic blood pressures at 5 time points were compared between the two treatment groups using repeated measures ANOVA. Table 4.4 shows the effects for systolic blood pressure. There was an overall significant change over time in both groups ( $p < 0.001$ ) but the change over time was not different according to treatment groups ( $p = 0.355$ ). Figure 4.8 shows that the decrease in systolic blood pressure over time was almost the same rate in both groups as the profiles are almost parallel. Therefore in terms of systolic blood pressure there was no statistical evidence for one treatment being more beneficial than the other.

**Table 4.4: Within- and between-subjects effects for systolic blood pressure**

Effect	Statistic	P value
Time	Wilk's lambda=0.133	<0.001
Time*group	Wilk's lambda=0.844	0.355
Group	F=0.258	0.615

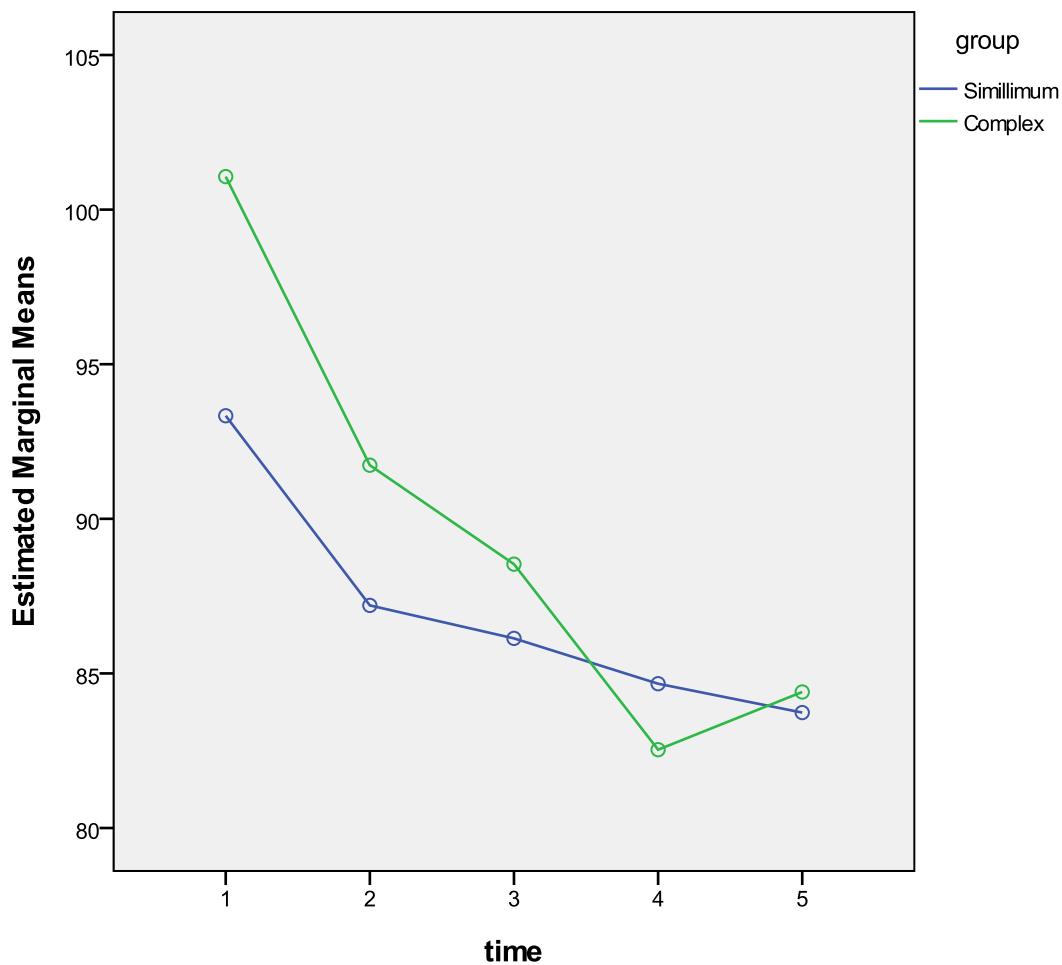


**Figure 4.8: Profile plot of mean systolic blood pressure over time by treatment group**

Table 4.5 shows the effects for diastolic blood pressure. There was an overall significant change over time in both groups ( $p < 0.001$ ) but the change over time was not different according to treatment groups ( $p = 0.187$ ). Figure 4.9 shows that the decrease in diastolic blood pressure over time was almost the same rate in both groups as the profiles are almost parallel. Therefore in terms of diastolic blood pressure there was no statistical evidence for one treatment being more beneficial than the other.

**Table 4.5: Within- and between-subjects effects for systolic blood pressure**

Effect	Statistic	P value
Time	Wilk's lambda=0.204	<0.001
Time*group	Wilk's lambda=0.789	0.187
Group	F=0.632	0.433



**Figure 4.9: Profile plot of mean systolic blood pressure over time by treatment group**

It is interesting to note the remedies most commonly prescribed. The full list of remedies prescribed and their frequency of prescription is to be found in Table 4.6.

**Table 4.6: Comparison of remedies used in each treatment group over time**

		group			
		Simillimum		Complex	
		Count	Column N %	Count	Column N %
Follow up 1	Arsenicum album	2	13.3%	1	6.7%
	Bryonia alba	2	13.3%	2	13.3%
	Calcarea carbonicum	1	6.7%	0	.0%
	Calcarea phosphorica	1	6.7%	0	.0%
	Gelsemium semperivens	0	.0%	2	13.3%
	Kalium carbonicum	1	6.7%	1	6.7%
	Kalium muriaticum	1	6.7%	0	.0%

	Lachesis muta	1	6.7%	1	6.7%
	Medorrhinum	0	.0%	1	6.7%
	Natrum carbonicum	1	6.7%	0	.0%
	Natrum muriaticum	0	.0%	2	13.3%
	Nux vomica	1	6.7%	0	.0%
	Phosphorus	1	6.7%	1	6.7%
	Pulsatilla	0	.0%	1	6.7%
	Rhus toxicodendron	0	.0%	1	6.7%
	Sepia officinalis	2	13.3%	2	13.3%
	Staphysagria	1	6.7%	0	.0%
Follow up 2	Aconitum napellus	1	6.7%	0	.0%
	Arsenicum album	0	.0%	1	6.7%
	Bryonia alba	1	6.7%	1	6.7%
	Calcarea carbonicum	1	6.7%	0	.0%
	Calcarea phosphorica	1	6.7%	0	.0%
	Kalium carbonicum	0	.0%	1	6.7%
	Lachesis muta	1	6.7%	0	.0%
	Lachesis Muta	0	.0%	1	6.7%
	Lycopodium clavatum	1	6.7%	0	.0%
	Magnesium phosphoricum	1	6.7%	0	.0%
	Natrum carbonicum	0	.0%	1	6.7%
	Natrum muriaticum	2	13.3%	4	26.7%
	Nux vomica	1	6.7%	1	6.7%
	Phosphoricum acidum	1	6.7%	0	.0%
	Phosphorus	1	6.7%	1	6.7%
	Pulsatilla	0	.0%	2	13.3%
	Rhus toxicodendron	0	.0%	1	6.7%
	Sepia officinalis	2	13.3%	1	6.7%
	Veratrum album	1	6.7%	0	.0%
	Follow up 3	Arsenicum album	1	6.7%	1
Belladonna		1	6.7%	0	.0%
Bryonia alba		1	6.7%	0	.0%
Calcarea carbonica		2	13.3%	1	6.7%
Calcarea phosphorica		1	6.7%	0	.0%
Gelsemium semperivens		1	6.7%	0	.0%
Kalium carbonicum		1	6.7%	0	.0%
Lachesis muta		0	.0%	1	6.7%
Natrum muriaticum		2	13.3%	4	26.7%
No script		1	6.7%	0	.0%
Nux vomica		1	6.7%	0	.0%
Phosphorus		0	.0%	1	6.7%
Pulsatilla		2	13.3%	2	13.3%

	Rhus toxicodendron	0	.0%	1	6.7%
	Ruta graveolens	0	.0%	1	6.7%
	Sepia officinalis	1	6.7%	2	13.3%
	Silicea	0	.0%	1	6.7%
Follow up 4	Alumina	1	6.7%	0	.0%
	Argentum nitricum	0	.0%	1	6.7%
	Arsenicum album	1	6.7%	1	6.7%
	Bryonia alba	2	13.3%	1	6.7%
	Calcarea carbonica	2	13.3%	1	6.7%
	Ignatia amara	0	.0%	1	6.7%
	Kalium carbonicum	1	6.7%	1	6.7%
	Lachesis muta	2	13.3%	2	13.3%
	Natrum muriaticum	1	6.7%	2	13.3%
	Phosphorus	0	.0%	1	6.7%
	Pulsatilla	2	13.3%	2	13.3%
	Rhus toxicodendron	0	.0%	1	6.7%
	Sepia officinalis	3	20.0%	0	.0%
	Silicea	0	.0%	1	6.7%

The data above thus suggests that no significant difference exists between the treatment effects of the simillimum versus the complex. This leads to the rejection of hypothesis 3 and acceptance of the null hypothesis.

### **Conclusion:**

Both the simillimum and complex treatments were effective at reducing blood pressure over time, but there was no evidence that one treatment was more beneficial than the other, since the rates of change over time in systolic and diastolic blood pressure were similar in both treatment groups.

## CHAPTER 5

### DISCUSSION

The results presented in the previous chapter, clearly illustrate the acceptance of the first and second hypothesis and a rejection of the third. This leads one to conclude that Homoeopathic treatment is effective in the treatment of Primary Hypertension, regardless of the preferred prescription method.

A review of the demographic pie charts indicate that 40 percent of participants were of African origin and 60 percent of participants were of Asian origin, with the majority of participants being between 51-65 years of age (40 percent). This correlates to the demographic data obtained from the South African Demographic and Health Survey (2003) which states that 40.1 percent of females between the ages of 55 and 64 suffer from high blood pressure and that more of the females in the Asian population suffer from Hypertension than in the African population.

Regarding the homeopathic prescriptions, it is interesting to note the remedies most commonly prescribed. Each prescription was based on a full, detailed homoeopathic case history (Appendix A) and physical examination (Appendix B). Analysis of the resulting case history resulted in the researcher arriving at the simillimum. This was the basis upon which the remedy was selected for each patient. The researcher used the homoeopathic materia medica and homoeopathic repertory to confirm the selection of each appropriate simillimum remedy.

As can be seen in Figure 4.3, *Natrum muriaticum*, *Sepia officinalis* and *Pulsatilla praetensis* were prescribed most commonly in the study. *Natrum muriaticum* was prescribed in 14.7 percent of the cases, *Sepia officinalis* in 10 percent of cases and *Pulsatilla praetensis* in 8.7 percent of cases.

*Sepia officinalis*, *Calcarea carbonica* and *Bryonia alba* were the most commonly prescribed remedies in the simillimum group. *Sepia officinalis* was prescribed in 12 percent of simillimum cases, *Calcarea carbonica* in 10.7 percent of cases and *Bryonia alba* in 9.3 percent of cases.

*Natrum muriaticum*, *Pulsatilla praetensis* and *Sepia officinalis* were most commonly prescribed in the complex group with *Natrum muriaticum* being prescribed in 20



percent of cases, *Pulsatilla praetensis* in 10.7 percent of cases and *Sepia officinalis* in 8 percent of cases.

Due to the high occurrence of *Sepia officinalis*, *Pulsatilla praetensis* and *Calcarea carbonica* in the study, it is interesting to note the cardiac symptoms reflected in the materia medica of the remedies as well.

Lilienthal (2006) describes *Sepia officinalis* having nervous palpitations which are worse when walking fast or for a long distance. Palpitations may also occur after emotions and anxiety over things that may have happened years ago. There may be a violent beating of the heart with interruption of the beats and congestion of blood in the chest with a sensation of great pressure more so on the left side. Vermeulen (2001) states that there may also be irregular circulation with overfull blood vessels and beating in all arteries.

*Pulsatilla praetensis* has been described by Vermeulen (2001) as having palpitations from emotions with shortness of breath and the beat of the pulse can be felt in the pit of the stomach. Lilienthal (2006) adds that *Pulsatilla praetensis* may also be used to treat rheumatic irritation of the heart, burning sensations in the cardiac region and hypertrophy and dilation of the right ventricle.

According to Lilienthal (2006), *Calcarea carbonica* has an anxious dread of heart disease with nervous palpitations and anxious restlessness occurring more often at night and after meals or slight exertion. There is also an inclination to draw a deep breath, with an unequal pulse and aneurism of the aorta. Vermeulen (2001) adds that the *Calcarea carbonica* patient may have a weak heart with a sensation of coldness and oppression of the chest.

Considering the characteristics of *Sepia officinalis*, *Pulsatilla praetensis* and *Calcarea carbonica*, it is understandable that they featured prominently in the study. However, these remedies were not included in the complex. It is also interesting to note that *Aurum metallicum* was not prescribed at all and *Veratrum album* was only prescribed once throughout the study. *Sepia officinalis*, *Pulsatilla praetensis* and *Calcarea carbonica* remedies are more indicated for use in female patients than *Aurum metallicum* and *Veratrum album* and hence in view of the simillimum results, it can be suggested that a separate standard complex be made for males and females. The

female complex would contain *Calcarea carbonica*, *Lachesis muta*, *Natrum muriaticum*, *Pulsatilla praetensis* and *Sepia officinalis* whilst the male complex would still contain *Aurum metallicum*, *Lachesis muta*, *Natrum muriaticum* and *Veratrum album*.

Although the study revealed positive results, certain methodological recommendations need to be considered. The follow up consultations occurred one week apart although patients may have benefited from longer periods between follow ups to allow the remedy prescribed a longer duration of action to be able to judge the medicine's effect on the maintenance of lower blood pressure levels.

## CHAPTER 6

### CONCLUSION AND RECOMMENDATIONS

#### 6.1 CONCLUSION

The purpose of this double-blind study was to evaluate the efficacy of the Homoeopathic simillimum and a Homoeopathic complex (*Aurum metallicum* 6CH, *Lachesis muta* 6CH, *Natrum muriaticum* 6CH, and *Veratrum album* 6CH) in the treatment of Primary Hypertension in adult females.

SPSS version 18 was used to analyse the data. A p value  $<0.05$  was considered as statistically significant. Repeated measures ANOVA tests were done to compare the blood pressures over time between the treatment groups. Specific remedies used at each time point were described by treatment group. Potencies of the remedies were compared within each remedy between the treatment groups using Pearson's chi square tests.

Within each of the two treatment groups there was a highly significant decrease in systolic blood pressure over time ( $p < 0.001$ ). This means that both treatments were effective at lowering systolic blood pressure.

Within each of the two treatment groups there was a highly significant decrease in diastolic blood pressure over time ( $p = 0.001$  and  $p < 0.001$  respectively). This means that both treatments were effective at lowering diastolic blood pressure.

Systolic and diastolic blood pressures at 5 time points were compared between the two treatment groups using repeated measures ANOVA. There was an overall significant change over time in both groups ( $p < 0.001$ ) but the change over time was not different according to treatment groups ( $p = 0.355$ ). The decrease in systolic blood pressure over time was almost the same rate in both groups as the profiles are almost parallel. Therefore in terms of systolic blood pressure there was no statistical evidence for one treatment being more beneficial than the other.

There was an overall significant change over time in both groups ( $p < 0.001$ ) but the change over time was not different according to treatment groups ( $p = 0.187$ ). The decrease in diastolic blood pressure over time was almost the same rate in both groups as the profiles are almost parallel. Therefore in terms of diastolic blood

pressure there was no statistical evidence for one treatment being more beneficial than the other.

Therefore, both the simillimum and complex treatments were effective at reducing blood pressure over time, but there was no evidence that one treatment was more beneficial than the other, since the rates of change over time in systolic and diastolic blood pressure were similar in both treatment groups.

The results of the study led to the conclusion that both treatment methods are effective in the treatment of Primary Hypertension in the African and Asian populations and that both treatment methods are equally as beneficial. Therefore Homoeopathic treatment of Primary Hypertension can be suggested for future treatment, with the Homoeopathic complex being used as a standard treatment method as it is time saving and can be standardised to be used in hospitals and clinics in the public sector with separate standard complexes being made for males and females in view of the results of this study. The female complex would contain *Calcarea carbonica*, *Lachesis muta*, *Natrum muriaticum*, *Pulsatilla praetensis* and *Sepia officinalis* whilst the male complex would contain *Aurum metallicum*, *Lachesis muta*, *Natrum muriaticum* and *Veratrum album* based on the results obtained from the study. The complex would remain at the 6cH potency to be taken as 10 granules three times a day as this proved to be effective in the study.

## **6.2 RECOMMENDATIONS**

This clinical study can be improved in the following ways:

- The period in which the trial runs could be extended to establish maximum decrease in blood pressure.
- The sample group could be increased to provide a greater statistical interpretation and to decrease margin of bias.
- The sample group could include males as well as females to establish if the treatment methods are effective in both genders.
- The blood pressure readings could be assessed using a computerised blood pressure cuff to eliminate human error, or an external person could be used to assess readings for verification.

- A comparative study, comparing the two Homoeopathic interventions against conventional antihypertensive drug therapy could be undertaken.
- Asses the efficacy of the common individual remedies prescribed in this study against placebo.
- The trial period could be extended to include blood pressure readings after the medication has been stopped, to assess the duration of action of the medication.
- A different potency of the complex could be used instead of 6cH, such as 12cH to assess if the higher potency is more effective at lowering blood pressure.

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## **APPENDIX A**

### Homoeopathic Case History

Date of case history: \_\_\_\_\_

Patient Number: \_\_\_\_\_

Surname: \_\_\_\_\_

First names: \_\_\_\_\_

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

Telephone no: (work) \_\_\_\_\_ (home) \_\_\_\_\_ (cell) \_\_\_\_\_

Age: \_\_\_\_\_ Marital status: \_\_\_\_\_ No. of children: \_\_\_\_\_

Occupation: \_\_\_\_\_

### Main Complaint

History, onset, location, aetiology, duration, character, modalities, concomitant symptoms, radiation, sensation.

### Past medical and surgical history

Any past surgeries or serious diseases that may or may not have required hospitalization.

### Past Drug History

Includes any medication the patient may have been on in the past or is currently taking.

### Vaccination

### Allergies

### Childhood Diseases

Mumps, measles, chicken pox, German measles, tuberculosis

### Family History

TB, diabetes, heart disease, hypertension, stroke, eczema, asthma, arthritis, sinusitis, hay fever, cancer, mental illness, miscarriage.

Father

Mother

Grandparents: Maternal and Paternal

Siblings

Children

### Social History

Drug abuse, smoking, alcohol: how much and how often

### Generals

Menses

Gastro-intestinal:   Appetite  
                                  Desires or cravings  
                                  Aversions  
                                  Aggravations or allergies  
                                  Bowel movements  
                                  Urination  
                                  Thirst

Energy levels

Weather preferences and modalities

Sleep: position, dreams

Perspiration including quantity and location

Libido

### Mental and Emotional

Fears, phobias, apprehensions, traumas, losses, grief, failure, worries.

### Systems Review

Head: Headaches, location, frequency, duration, sensation, modalities

Hair: hair loss, change in texture

Eyes: Vision, pain, redness, discharge

Ear: Hearing difficulties, tinnitus, vertigo, earache, discharges, itching

Nose and Sinuses: Pain, congestion, discharge, hay fever or sinusitis, rhinitis, smell

Teeth: loss of teeth, discolouration

Throat: Pain, dysphagia, swollen glands

Respiratory system: difficulty breathing, cough, sputum, asthma, TB

Cardiovascular system: Chest pain, hypertension, heart disease

Gastro-intestinal system: Bowel habits, haemorrhoids, bleeding, abdominal pain, flatulence, gastric ulcers, colitis, Irritable bowel syndrome

Urogenital system: difficulty urinating, frequency, colour, rashes, sores, warts, leucorrhoea

Musculo-skeletal: arthritis, joint pain, stiffness, gout

Neurological: numbness, paralysis, loss of function, weakness

Endocrine: Thyroid function, Diabetes

Skin: acne, warts, eczema, psoriasis, fungal infections

Nails: deformation, brittleness, marks or colours

## **APENDIX B**

### **Physical Examination**

**General observation:** level of consciousness, signs of distress, skin colour, demeanour and gait, stature and build, body odour, dress, personal hygiene.

### **Vitals:** Pulse

Temperature

Blood Pressure

Respiration rate

Weight and Height

Head: Inspect and palpate the scalp and the hair

Check for dandruff, lice, lumps, masses

Face: Inspect, palpate

Check for facial oedema, involuntary movements, symmetry swollen lymph nodes, skin lesions, moles, hair distribution

APPENDIX C

DO YOU SUFFER FROM  
HYPERTENSION OR HIGH BLOOD  
PRESSURE?

SHOULD YOU QUALIFY...

FREE TREATMENT FOR 30 FEMALES BETWEEN  
THE AGES OF 18 AND 65.

IF YOU ARE NOT CURRENTLY ON ANY MEDICATION  
AND WOULD LIKE TO PARTICIPATE IN RESEARCH  
BEING DONE AT DURBAN UNIVERSITY OF  
TECHNOLOGY DEPARTMENT OF HOMOEOPATHY  
OR WOULD LIKE TO KNOW MORE....

CONTACT: RAEESA ON 083 779 7258

Or



# THE HOMOEOPATHIC DAY CLINIC ON

031 373 2041

## APPENDIX D

### Letter of Information and Consent

**Title of the Research Study:** A comparison of the efficacy of two Homoeopathic interventions in the treatment of Primary Hypertension in adult females.

**Principle Investigator/s:** Raeesa Aboobaker

**Co-Investigator/s:** Dr Izel Botha (D.Tech Homoeopathy)

**Brief Introduction and Purpose of the Study:** I am a master's student at the Durban University of Technology. In order to qualify as a Homoeopath I need to complete a dissertation. I therefore appeal for your assistance in giving me as many accurate symptoms as possible, to enable accurate completion of my research on the treatment of Hypertension. This is a double blind study which means 15 of the 30 participants will receive a Homoeopathic simillimum and the other 15 will receive a Homoeopathic complex. The medicines that you will receive will be in the form of powders, granules and drops.

**Outline of the Procedures:** The double blind trial will take place in the afternoons at the homoeopathy day clinic at the Durban University of Technology. Treatment will be under the supervision of a qualified and registered homoeopath.

In order to participate in this trial, you will need to fulfil the following criteria:

- Females between the ages of 18 and 65
- Patients conforming with the diagnostic criteria for hypertension as defined by the JNC VII
- or already being diagnosed by a Primary Health Care Provider, General Practitioner or Physician.

The following criteria would exclude you from participating in the trial:

- Breastfeeding or pregnant women
- Individuals younger than 18 or older than 65
- Malignant hypertension
- Hypertension above 190mmHg over 120mmHg
- Patients currently on any medication that would have an effect on the blood pressure. Please note that patients will not be allowed to participate if they stop current medication in order to join the study
- Patients with renal or endocrine disease or with a history of Cardiac surgery.

Once you have fulfilled the above mentioned criteria you will be accepted to participate in the trial. Treatment will involve five consultations, an initial, and four follow-ups with 1 week between each. At each consultation you will be given remedies. All the information obtained from the consultation will be kept confidential.

This is a double blind study which means 15 of the 30 participants will receive a Homoeopathic simillimum and the other 15 will receive a Homoeopathic complex. The medicines that you will receive will be in the form of powders, granules and drops.

**Risks or Discomforts to the Subject:** There are no known or potential risks

**Benefits:** Patients in all groups will benefit from the treatment as each will receive a different form of treatment for Hypertension.

**Reason/s why the Subject May Be Withdrawn from the Study:** A participant will be removed due to non compliance or severe illness. Participants are free to withdraw from the study at any time without risk or consequences.

**Remuneration:**The participant will receive treatment for Primary Hypertension at no cost.

**Costs of the Study:** All medication and consultations will be provided free of charge for the duration of the study.

**Confidentiality:** All information will be kept confidential at all times. Participants will be issued with a number, meaning that no names or personal identifiers will be present on any data collected.

**Research-related Injury:** No research related injury is expected as all treatment forms are free of side effects. In the unlikely event of an adverse effect occurring, treatment will be provided free of charge.

**Persons to Contact in the Event of Any Problems or Queries:**

Dr Izel Botha (Supervisor): 031 373 2514

**Statement of Agreement to Participate in the Research Study:**

I,.....subject's full name, ID number....., have read this document in its entirety and understand its contents. Where I have had any questions or queries, these have been explained to me by .....to my satisfaction. Furthermore, I fully understand that I may withdraw from this study at any stage without any adverse consequences and my future health care will not be compromised. I, therefore, voluntarily agree to participate in this study.

Subject's name (print) ..... Subject's signature:.....Date:.....

Researcher's name (print): .....Researcher's signature:.....Date:.....

Witness name (print) signature: .....Witness signature:.....Date:.....

Supervisor's name (print):.....Supervisor's signature: .....Date:.....