

A placebo controlled study determining the effectiveness of a homoeopathic complex (Caladium seguinum 30CH, Nux vomica 30CH, and Staphysagria delphinium 30CH) as compared with homoeopathic similimum treatment in the management of tobacco addiction.

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Mini-Dissertation submitted in partial compliance with the requirements of the Master's Degree in Technology: Homoeopathy in the Faculty of Health Sciences at the Durban Institute of Technology.

I Sapna Lutchman-Maharaj do declare that this mini-dissertation is representative of my own work, both in conception and execution.

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*For, my parents (Rajan & Anita Lutchman)  
As well as my late grand mum (Mrs. Sheila Singh)*

*Thank you for all your support, guidance and encouragement in all  
endeavours of my life. Without the love and wisdom, you have imparted  
to me, I would not have achieved all that I have.*

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## **ABSTRACT**

A sudden decrease in the use of nicotine containing products, which was used daily for at least several weeks, can cause Nicotine Withdrawal Syndrome (American Psychiatric Association, 1994: 244). The mental symptoms of the withdrawal syndrome includes depressed mood; irritability, frustration, anger, anxiety, difficulty concentrating, restlessness or impatience.

The aim of this placebo-controlled double-blind study was to determine the effectiveness of a homoeopathic complex, compared to homoeopathic similimum treatment in the management of tobacco addiction. The complex was based on the selection of those homoeopathic remedies whose symptomology most accurately matched the symptoms associated with smoking cessation.

The study was designed for 30 participants, consisting of three equal random groups, with one group receiving the complex, the second receiving the similimum and the third group receiving placebo treatment. However, extra participants were recruited to allow for dropouts and statistical analysis was made from all participants who completed the study. The final number of participants that completed the study was 43. The participants had a follow up consultation 2 weeks after the initial consultation and a second follow up 4 weeks after the initial consult.

The data for this study was obtained from the Smoking Log Sheets (Appendix F) and the Tolerance Dependence Questionnaires (Appendix C). To evaluate the validity of this questionnaire, the researcher conducted a pilot study, consisting of smokers and non-smokers. The smoking log sheets provided an objective measurement and the tolerance dependence questionnaire was subjective.

For each type of scale, the Wilcoxon Signed Rank Test was conducted to test for a significant difference in population means within each group i.e. before and after treatment. The difference between the pre-treatment and post-treatment within each group was calculated. All the results were positive i.e. there were significant differences within each of the three groups on both scales, where  $p < 0.05$ . This new column of differences within group was then compared across all groups using the Kruskal Wallis Test. This test revealed no significant differences between groups for the Smoking Log Sheets ( $p = 0.978$ ) and the Tolerance Dependence Questionnaire ( $p = 0.934$ ).

The treatments administered in this study, including placebo, were successful in bringing about a significant reduction in the number of cigarettes smoked and the symptoms of dependence, but because there was no significant difference in effect between the homoeopathic medicines and the placebo, it is concluded that the homoeopathic medicines *per se* were not effective in the management of tobacco addiction.

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## DEFINITION OF TERMS

**Arrhythmia:** any deviation from the normal rhythm of the heart (Martin, 2000: 45).

**Catecholamines:** a group of physiologically important substances, including adrenaline, noradrenaline and dopamine, having various roles (mainly as neurotransmitters) in the functioning of the nervous system (Martin, 2000: 107).

**CH:** refers to the **Centesimal Scale “C”** prepared by the **Hahnemannian method of potentisation**.

**Centesimal Scale “C”:** A method of potentising based on the principal that the first potency should contain one hundredth part of the base drug and each succeeding potency should contain 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).

**Crohn’s disease:** a condition where segments of the alimentary tract gets inflamed, thickened and ulcerated. It usually affects the terminal part of the ileum. Crohn’s disease often causes partial obstruction of the intestine leading to pain, diarrhea and malabsorption (Martin, 2000: 156).

**Dopaminergic:** Dopamine is a neurotransmitter which stimulates the release of noradrenaline from nerve endings. It acts on the limbic system which is involved in the expression of instinct and mood. Dopaminergic therefore refers to the activation of the dopamine pathways (Martin, 2000: 193; 372).

**Hahnemannian method of potentisation:** a method of potentisation introduced by Samuel Hahnemann, whereby a separate sterilized dropper is used for each dynamization. The symbol “H” after the potency scale is used to denote this, as in 30CH (Gaier, 1991: 456).

**Isotherapy:** Isotherapy is the use of the ‘same’ (iso-) instead of the ‘similar’ (homoeo-) as medicines for curing disease (Gaier, 1991: 290).

**Placebo:** A non-medicated substance, that is relatively inert pharmacodynamically administered to contract the effects of relative non-medication in controlled experiments with those of medication in two comparable groups of participants (Gaier, 1991: 426).

**Potency:** The stage of altered remedial activity to which a drug has been taken by means of a mathematico-mechanical process of deconcentration with succussion, or by trituration of the medicinal substance, which is thus brought to a state of diminutive or infinitesimal subdivision (Gaier, 1991: 432).

**Similimum:** The homoeopathic remedy, chosen from the entire range of Homoeopathic remedies, whose pathogenetic action matches the symptom picture of the participant (Jouanny, 1991: 92).

**Tolerance:** develops after taking a drug for a long period of time. In such cases increased doses are necessary to produce the desired effect (Martin, 2000: 661).



# CHAPTER 1

## 1.1 Introduction

There are 1.1 billion smokers worldwide, which equals about one third of the global population aged 15 years and older. Tobacco smoke contains more than 4000 toxic chemicals. These chemicals can cause disease whether tobacco is chewed or inhaled <sup>19</sup> (World Health Organization, 2001:slide 2; 5). Smoking accounts for one in every 7 cancer cases worldwide <sup>20</sup> (World Health Report, 1997). Statistics show that tobacco kills more people than AIDS, drugs, accidents and alcohol together (Serfontein, 2001:34). According to a report in the American Journal of Public Health, people who stop smoking can live a lot longer, regardless of the age at which they quit. The study found that younger people benefit the most, but even those who are 65 can add years to their life by quitting” <sup>1</sup>(American Cancer Society, 2002: 52:319).

*Although over 80% of individuals who smoke express a desire to stop smoking, and 35% try to stop each year, less than 5% are successful in unaided attempts to quit (American Psychiatric Association, 1994:243).*

Smoking cessation may change the balance of neuro-chemical modulators of moods. Depressed mood, anxiety, irritability and fatigue are all symptoms, which often peak within a few days after smoking cessation. When depressive symptoms emerge during withdrawal from nicotine, the likelihood is higher for both cessation failure and relapse (Samet and Yoon, 2001). This study aims to address the problem of nicotine addiction via the depressive symptoms that arise from smoking cessation, as it is the most difficult of the withdrawal

symptoms to overcome and will also decrease the number of relapses that occur.

In a South African study, conducted by the University of Cape Town's School of Economics, the number of smokers since 1993 has dropped by a third. The researcher, Van Walbeek, says that poorer, mostly black people are quitting; showing that the state's strategy of raising tobacco taxes is helping to discourage smoking. Van Walbeek also said that while cigarette prices were putting South Africans off smoking, in developed countries, a decrease in cigarette sales was due to increased health awareness. Van Der Merwe, chairman of the Tobacco Institute of Southern Africa, said that although fewer packs of cigarettes were being sold over the counter, this did not mean that people were smoking less, but that smuggling was on the increase (Lombard, 2004:5).

De la Rouviere, (1996) evaluated the efficacy of acupuncture and homoeopathic treatment in helping people to stop smoking. The finding was that there was a cessation rate of 40% in the homoeopathic group and 33% of the acupuncture group. Although there was no statistical difference between the groups after treatment, the homoeopathic treatment group showed a 7% improvement over the acupuncture group. Another study conducted by Pautz, (1998), investigated the relative effectiveness of isotherapy compared to isotherapy and similimum in managing tobacco smoking addiction. She found that managing tobacco addiction is more effective when using isotherapy together with homoeopathic similimum. Hellberg (2001), evaluated the

efficacy of an over the counter complex, Anti-Tobacco® complex in helping people to stop smoking. The results indicated that the complex did not reduce cigarette consumption.

This trial evaluated the efficacy of a new complex, using *Caladium seguinum*, *Nux vomica* and *Staphysagria delphinium*, as recommended by Hellberg (2001), with all the remedies being used in the 30CH potency. The aim of this study was to determine the efficacy of a homoeopathic complex, as opposed to homoeopathic similimum treatment in the management of tobacco addiction. The complex was based on the selection of those homoeopathic remedies, whose symptomology most accurately matched the depressive symptoms associated with smoking cessation.

This study was aimed at treating tobacco addiction but in order to do this the nicotine withdrawal syndrome was taken into consideration when choosing the remedies in the complex to act by virtue of the homoeopathic principle, “Like Cures Like” (Vithoulkas, 1986:92).

Nicotine withdrawal symptoms increases the likelihood of cessation failure and relapse. (Samet and Yoon, 2001) Nicotine withdrawal syndrome develops after the abrupt cessation of, or reduction in, the use of nicotine-containing products following a prolonged period of daily use. The withdrawal syndrome includes dysphoric or depressed mood, insomnia, irritability, frustration, anger, anxiety, difficulty concentrating, restlessness or impatience (American Psychiatric Association, 1994: 244).

## **1.2 Objectives**

### **1.2.1 1<sup>st</sup> Objective**

To determine the effectiveness of the homoeopathic complex containing Caladium seguinum (30CH), Nux vomica (30CH) and Staphysagria delphinium (30CH) compared to similimum treatment in the management of tobacco addiction in terms of frequency, using the Smoking Log Sheets.

### **1.2.2 2<sup>nd</sup> Objective**

To determine the effectiveness of the homoeopathic complex containing Caladium seguinum (30CH), Nux vomica (30CH) and Staphysagria delphinium (30CH) compared to similimum treatment in the management of tobacco addiction in terms of symptoms of tolerance, using the Tolerance Dependence Questionnaire.

## **1.3 Statement of hypotheses**

### **1.3.1 The first hypothesis**

It is hypothesised that the homoeopathic complex containing Caladium seguinum 30CH, Nux vomica 30CH and Staphysagria delphinium 30CH will

not be effective in reducing frequency as measured by the Smoking Log Sheet scores.

### 1.3.2 The second hypothesis

It is hypothesised that similimum treatment will not be effective in reducing frequency as measured by the Smoking Log Sheet scores.

### 1.3.3 The third hypothesis

It is hypothesised that the homoeopathic complex containing Caladium seguinum 30CH, Nux vomica 30CH and Staphysagria delphinium 30CH will not be effective in reducing tolerance symptoms as measured by the Tolerance Dependence Questionnaire scores.

### 1.3.4 The fourth hypothesis

It is hypothesised that similimum treatment will not be effective in reducing tolerance symptoms as measured by the Tolerance Dependence Questionnaire scores.

### 1.3.5 The fifth hypothesis

It is hypothesised that there will be no difference in effect between the homoeopathic complex, the similimum, and the placebo in reducing frequency as measured by the Smoking Log Sheet scores.

### 1.3.6 The sixth hypothesis

It is hypothesised that there will be no difference in effect between the homoeopathic complex, the similimum, and the placebo in reducing tolerance symptoms as measured by the Tolerance Dependence Questionnaire scores.

## CHAPTER 2

### REVIEW OF THE RELATED LITERATURE

#### 2.1 Introduction

In 1992, the Medical Research Council estimated that 25000 deaths a year were due to tobacco-related diseases in South Africa. New data suggests that more deaths from smoking may be attributable to tuberculosis than to lung cancer in South Africa, as smoking increases the risk of dying from tuberculosis by 60%. Approximately 2 out of 3 adolescent smokers tried quitting but only 27% succeeded in doing so. A case study conducted at Garankuwa Hospital between 1993 and 1995 found that male smokers were ten times more likely to get lung cancer than male non-smokers and that women smokers had a five fold higher risk. This level of risk is similar to that found in high-income countries in the 1960s and 1970s, which shows that the epidemic is still at an early stage and it's full effect still remains to be felt, considering that the Northern Province has the lowest smoking prevalence rate in the country (Health Systems Trust, 2000:432).

## 2.2 Smoking and addiction

Once a person starts smoking, they are almost guaranteed to get addicted. Nicotine has such a powerful effect on the brain that the adaptation mechanism reacts extremely quickly, thereby making one physically addicted within weeks. The degree to which people experience these symptoms ranges enormously. For thousands of participants, the withdrawal symptoms are enough to stop their attempts to quit smoking (Brynin, 1995:49-50).

More than 90 percent of smokers who try to quit without seeking treatment fail, with most relapsing within a week. Tolerance refers to a condition where higher doses of a drug are required to produce the same initial stimulation. Nicotine is metabolized rapidly and disappears from the body within a few hours. Therefore tolerance can be lost overnight and smokers report that the first cigarettes of the day are the best <sup>11</sup>(National Institute on Drug Abuse, 1998).

According to Ross (2002), most addicts are born with subnormal moods and most of them come from families where addiction and depression or other mood problems have been noted. This occurs because they can inherit a deficiency in the production of natural mood boosters produced by the brain. The important genes in addiction are the ones that program the brain's mood functions and should they be "faulty", they can program deficiencies in particular brain sites that result in "built-in bad-mood states". Depending on the inherited deficiency i.e. serotonin, nor-epinephrine, endorphin and/ or

GABA, there will be an attraction to drugs that affect that particular deficiency zone/s (Ross, 2002:251-254).

According to Piasecki and Newhouse (2000), smoker's generally smoke for the pleasurable-relaxing effects, the stimulating effects and to reduce negative feelings. Groups of individuals with various psychiatric disorders display a higher incidence of smoking. According to a study conducted by Breslau (1995), quoted by Piasecki and Newhouse nicotine dependence was associated with a history of major depression, anxiety disorders, early conduct problems and abuse of alcohol and other illicit drugs. Neuroscientists believe that a relationship exists between nicotine and dopaminergic systems, which act as an aid to learning, and this can possibly explain why drug addicts continue to abuse drugs even when the euphoric effects of the drug has worn out (Piasecki and Newhouse, 2000:94-118).

### **2.3 Nicotine withdrawal symptoms**

According to the Diagnostic and Statistical Manual of Mental Disorders, (American Psychiatric Association, 1994), the diagnostic criteria for nicotine withdrawal are as follows:

- A. Daily use of nicotine for at least several weeks
- B. Abrupt cessation of nicotine use, or reduction in the amount of nicotine used, followed within 24 hours by four (or more) of the following signs:
  - Depressed mood
  - Insomnia

- Irritability, frustration or anger
- Anxiety
- Difficulty concentrating
- Restlessness
- Decreased heart rate
- Increased appetite or weight gain

C. The symptoms in Criterion B cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.

D. The symptoms are not due to a general medical condition and not better accounted for by another mental disorder.

The above symptoms are more intense in those who smoke cigarettes than those who use other nicotine-containing products.

Withdrawal symptoms are also associated with a slowing on EEG, a decrease in catecholamine and cortisol levels, impairment on neuropsychological testing and decreased metabolic rate. The metabolism of many substances as well as medications, prescribed for mental disorders, is increased by smoking. Therefore there is an increase in blood levels of these medications and substances to a clinically significant degree, upon smoking cessation (American Psychiatric Association, 1994:244-245).

## 2.4 Smoking and negative mood

Carr (1991:108) states that a positive mental approach is essential – always. Smoking also has an effect on the stress mechanism. It does this by raising the blood sugar levels and promoting the production of adrenalin therefore stimulating the stress response. Paradoxically, it also acts as a narcotic and slows down brain activity. Nicotine can therefore be used in opposite ways: a short puff on a cigarette will supply enough nicotine to the brain to stimulate it and a long drag has a narcotic effect. Therefore, a tired person will instinctively take short puffs and a stressed person will take long drags. However due to the addictive nature of the drug, the person gets stuck with a dependence on the drug to control the stress response (Brynin, 1995:91).

People who smoke every day are twice as likely to suffer from depression as people who don't smoke. Studies have found that people with major depression are three times more likely to be daily smokers and that nicotine is a drug that is craved to medicate depressed moods (Rosenthal, 2002:118).

Piasecki and Newhouse (2000) report on a study conducted by Glassman et al (1998) which found that participants with a past diagnosis of major depression had a poorer success rate with cessation (33%) as opposed to participants with no history of depression (57%). In another study, Glassman describes 9 psychiatric casualties with such extreme depressive features following cessation, that they were advised to resume smoking and also received anti-depressant medication. In 1995, Dalack compared smokers with

a history of major depression to those who never experienced depression. Participants with a history of major depression were treated with antidepressants 3 weeks before the quit date. He noted that the group treated with the antidepressants showed significant improvements and concluded that although 3 weeks may not be adequate pre-treatment period, some smokers with sub-syndromal depression may respond to treatment with antidepressants (Piasecki and Newhouse, 2000:134-135).

## **2.5 Gender differences in quitting smoking**

The <sup>12</sup> National Institutes of Health (2001) reported on a review done by <sup>13</sup> Perkins (2001), which found that women suffer greater risks of smoking-related diseases than men. In one study reviewed by Perkins, women smokers had had a double risk of myocardial infarction than men. There is also a further exacerbation in the risk of heart attacks and strokes in women smokers who use oral contraceptives. Some of the studies also conclude that women may have nearly double the risk of lung cancer as opposed to men. Females who smoke find it more difficult to fall pregnant and reach menopause a year or two younger than women who do not smoke. Perkins also found that since a female's menstrual cycle affects tobacco withdrawal symptoms, a female's response to anti-smoking drugs might vary by cycle phase <sup>12</sup>(National Institutes of Health, 2001).

Withdrawal symptoms can be very distressing and are similar to the symptoms associated with premenstrual tension, which include anxiety,

depression, abdominal bloating, backache, headache, irritability and mood swings. According to researchers, women who quit smoking during the luteal phase of the menstrual cycle (day 15 or more) experienced greater tobacco withdrawal symptoms than women who quit smoking during the follicular phase (day 1-14). These results were also true for women who were on oral contraceptives <sup>13</sup>(Perkins, Levine and Marcus, 2000).

According to findings from the Lung Health Study (LHS), which followed more than 5,300 middle-aged smokers for five years, women's lung function improves significantly more than men's after sustained smoking cessation. Previously published research by the LHS shows that men and women benefit from smoking cessation, but benefits to the lungs are greater in women than in men <sup>10</sup>(National Heart, Lung, and Blood Institute, 2003).

## **2.6 Smoking and pregnancy**

Smoking during pregnancy is recognized as the most preventable risk factor for an unsuccessful pregnancy outcome. Smoking is associated with foetal growth restriction, and increasing evidence suggests that smoking may cause stillbirth, preterm birth, placental abruption, and also sudden infant death syndrome. Smoking during pregnancy also increases risks of spontaneous abortions, ectopic pregnancies, placenta previa and may increase risks of behavioural disorders in childhood <sup>3</sup>(Cnattingius, 2004).

In a study conducted at the Mount Sinai School of Medicine in New York City, mothers who smoked during pregnancy found that their children exhibited more negative behaviours, such as impulsiveness, risk-taking and rebelliousness, than mothers who did not smoke during pregnancy. The mother's disciplinary style could have also been linked to this behaviour; therefore researchers adjusted for this factor and found that a mother's smoking during pregnancy independently increased the risk of negativity at the age of 2, by fourfold. These findings could be due to disturbances in the neurophysiological functioning of the foetus, caused by maternal smoking during pregnancy <sup>17</sup>(Thomas, 2001).

Researchers also found that maternal smoking during pregnancy has long-term effects on children's behaviour and health, which could not be explained by any other factor in the study. If mothers smoked more than 10 cigarettes a day during pregnancy, the risk for adolescent drug abuse in girls was more than 5-fold higher and the risk for onset of conduct disorder was 4-fold greater for boys. Why girls exposed to smoking before birth should be at risk for drug abuse and boys for conduct disorder still remain to be understood. The differences could be related to sex differences in prenatal brain development <sup>18</sup>(Varisco, 2000).

A study was conducted to assess the effects of smoking during pregnancy on lung mechanics and lung volumes in the immediate neonatal period, before infants are exposed to passive smoking. It was found that smoking during pregnancy has an adverse effect on birth weight, length, head and chest

circumference. The lungs of boys born to smoking mothers have reduced compliance. The lungs of girls born to smoking mothers have increased airways resistance <sup>9</sup>(Milner, et al., 1999).

## **2.7 Smoking and diet**

Smoking does carry risks but they can be reduced. Smokers are likely to be short of vitamins A, C, E, folic acid, several other B vitamins and the minerals calcium, selenium and zinc. Antioxidants and antioxidant nutrients such as vitamin E and C are required more in smokers than average people. Smokers should also limit tea and coffee intake. It is preferable for smokers to have fruit or vegetable juices or herbal teas. The original smoking studies conducted in the US and UK showed that the risk of cancer was proportionate to the number of cigarettes smoked and the tar content. It was shown that smokers, who did not get cancer, on average, ate foods rich in antioxidants, which can reduce the risk of cancer, heart disease and cataracts. The diet of this group of smokers also included the B vitamins, vitamin E and vitamin C (Scala, 1993:1-6).

## **2.8 Medical consequences of smoking**

### **2.8.1 Smoking and Cancer**

When tobacco is burned, tars and other combustion by-products are released and these contain highly carcinogenic free radical compounds. These compounds react with cells and deplete a form of homocysteine (thioretinaco) from the cell membranes and thereby transform normal cells into cancer cells. There is a greater risk of cancer of the mouth, oesophagus and larynx in smokers who also abuse alcohol because the alcohol makes the effect of carcinogens on cells worse (McCully, 1999:134).

Lung cancer is the most common form of cancer in industrialized countries. The most important cause for lung cancer is tobacco smoke, and with increased sales, a major epidemic is predicted for both Asia and Africa<sup>6</sup>(Lam, White, and Chan-Yeung, 2004).

### **2.8.2 Smoking and Coronary Heart Disease**

Tobacco use causes more deaths by cardiovascular diseases than by cancer. Approximately one third of all Americans who die of heart disease and stroke are younger than sixty-five and a quarter of these deaths are due to tobacco use (VanderVeen, Stewart and Heritage, 1989: 40-41).

Smoking also accounts for the increase in incidence and severity of atherosclerosis in women. One or more packs of cigarettes smoked per day for several years, increases the death rate from ischemic heart disease by 200 percent (Kumar, Cotran, and Robbins, 1997: 284).

### 2.8.3 Smoking and Lung Disease

Carbon monoxide, a gas found in cigarette smoke, destroys the lung's elastic tissue therefore all smokers suffer damage to their lungs. After smoking over a period of years, this leads to chronic infections, increased fibrous tissue, and stiffness of the lung and over expansion of the lung. This is known as emphysema and chronic bronchitis, which are also causes of death in smokers (McCully, 1999:134).

### 2.8.4 Smoking and the Digestive System

Smoking contributes to problems such as heartburn, peptic ulcers, liver disease and Crohn's disease. Normally, the acid solution is kept in the stomach by a muscular valve at the lower end of the oesophagus, which is weakened by smoking, therefore allowing a backflow of the acid from the stomach into the oesophagus. Smoking can also cause direct injury to the oesophagus, making it more prone to damage from the reflux material.

There is a higher risk of Crohn's disease in both current and former smokers as opposed to non-smokers. A higher rate of relapse, repeat surgery and immunosuppressive treatment is associated with smoking (Hoffman, 2001:13-14).

Smoking confers a greater risk of gastric ulcers and to a lesser extent, duodenal ulcers. Once the ulcer has formed it is likely to create complications and is less likely to heal on standard treatment regimens, if the patient continues to smoke (Haslett, et al., 2000: 633).

#### 2.8.5 Health consequences in children of smokers

Cot death also known as Sudden Infant Death Syndrome is the sudden, unexplained death of an infant in the first year of life. The British Medical Association (BMA) quotes the UK Confidential Inquiry into Stillbirths and Death in Infancy, which estimated that the risk of cot death increased by 2.5 times in families where only the father smoked. The risk increased almost four times in families where both parents smoked. According to the BMA, parental smoking is also an important cause of lower respiratory tract illness in infants and children, including croup, bronchitis, bronchiolitis and pneumonia (British Medical Association, 2004: 21-23).

## **2.9 Health benefits of quitting**

Within twenty minutes of quitting, blood pressure readings return to the level that they were before the last cigarette was smoked. At the same time the temperature of the hands and feet will return to normal. Within eight hours the carbon monoxide in the blood will return to normal. In twenty-four hours the risk of a heart attack will decrease to pre-existing levels. Within two to twelve weeks the vascular system and the circulation improves and lung function increases by thirty percent. Within the first nine months, structures within the respiratory tract that are responsible for clearing mucous from the lungs, re-grow and improves the lungs ability to cope with infections and toxins. A year later the risk of a heart attack decreases by fifty percent and five to fifteen years later, the risk of a stroke will decrease to that of a non-smoker. Ten years later the risk of developing a lung cancer will be fifty percent than that of a smoker (Serfontein, 2001: 34-35).

## **2.10 Nicotine replacement therapy (NRT)**

Nicotine replacement therapy (NRT) is available in different forms (gum, transdermal patch, nasal spray, inhaler, sublingual tablet and lozenge). Most NRT forms deliver nicotine more slowly than smoking and therefore the increase in nicotine blood levels is more gradual. The nasal spray provides faster withdrawal relief than any other form of NRT, however, absorption is slower and blood levels of nicotine are lower, than with smoking. According to

Le Houezec, these differences in pharmacokinetics as compared to smoking, may explain why some smokers still have difficulties in quitting, even while using NRT <sup>8</sup>(Le Houezec, 2003).

#### 2.10.1 Nicotine gum

According to a double-blind placebo-controlled trial, which evaluated the efficacy of nicotine gum in alleviating acute cravings for cigarettes, both nicotine and placebo gum are equally effective at reducing acute cravings for cigarettes <sup>4</sup>(Davies, et al., 2004).

Nicotine chewing gum is less important than one's will in giving up smoking. It may be that chewing gum with no pharmacological content may substitute the habit of using the mouth (Voss, 1992: 92).

Common side effects associated with the nicotine gum are gastric irritation and hiccups, throat irritation and flatulence. Excessive chewing can also cause the temporo-mandibular joints to become painful (Beers and Berkow, 1999:2488-2489).

#### 2.10.2 Nicotine patch

A trial, conducted at the University of Stellenbosch, was used to determine whether a 2-week pre-treatment with trans-dermal nicotine influences withdrawal symptoms and abstinence rates in smokers subsequently quitting

with the nicotine patch. It was found that there was no significant difference in withdrawal symptoms. Even though the nicotine patch pre-treatment did not reduce early withdrawal symptoms, it did increase sustained abstinence rates at six months <sup>16</sup>(Schuurmans, et al., 2004).

The patch delivers a steady level of nicotine throughout the day. According to the Cochrane Tobacco Addiction Review Group, wearing the patch for sixteen hours a day is as effective as wearing it for twenty four hours a day. They also found that eight weeks of patch therapy is as effective as longer courses and that there is no evidence that tapered withdrawal is better than abrupt withdrawal <sup>7</sup>(Lancaster, et al., 2000).

### 2.10.3 Nicotine nasal spray

This is the most powerful type of NRT and is generally used for the heavier more dependant smokers who failed at many other interventions, which were unable to reduce their cravings. It is not used as the first line treatment for light and medium smokers. The nicotine nasal spray delivers a shot of nicotine very rapidly through the lining of the nose therefore helping with cravings quickly. The disadvantage of using the nicotine nasal spray is that it initially causes the eyes to water; it causes nasal irritation and sneezing. Since the nicotine nasal spray is the strongest and quickest replacement method of delivering nicotine, it is also more likely to cause dependence (Willis, 2000:66-67).

A study examining the acute effects of nicotine replacement therapy via nicotine nasal spray (fast delivery) and transdermal nicotine patch (slow delivery), found that in acute conditions, the speed of nicotine delivery by nicotine spray vs. patch differentially affected cardiovascular responses and perhaps craving, but did not influence withdrawal <sup>14</sup>(Perkins, et al., 2004).

#### 2.10.4 Nicotine inhaler or inhalator

Most of the inhaled nicotine is absorbed via the buccal mucosa. The inhaler is contra-indicated in women who are or may become pregnant, as it may cause foetal harm. It is also contra-indicated in participants during the immediate period after a heart attack, life-threatening arrhythmias, participants with severe or worsening angina pectoris, non-tobacco users, participants intolerant of nicotine and menthol as well as in participants with active temporo-mandibular joint disease. The most frequent adverse effects are local irritation of the mouth and throat as well as cough (Pharmacia South Africa, 2000).

#### 2.10.5 The microtab

The microtab supplies a steady dose of nicotine to help reduce cravings. The difference between the microtab and the gum is that the microtab is allowed to dissolve slowly under the tongue, instead of being chewed. The microtab

takes approximately twenty to thirty minutes to dissolve completely and the nicotine is slowly absorbed the lining of the mouth. The same amount of relief is obtained as that obtained from 2mg nicotine gum. The amount of microtabs to be used depends on the number of cigarettes smoked by the individual. If less than twenty cigarettes are smoked per day, then eight to twelve microtabs are to be used per day. If more than twenty cigarettes are smoked per day sixteen to twenty-four microtabs are to be used per day. If the tablets are swallowed then the nicotine passes into the stomach and is therefore not absorbed, resulting in wastage of the microtab (Willis, 2000:69-70).

## **2.11 Other interventions used to stop smoking**

### **2.11.1 Behavioural and psychological intervention**

According to the Cochrane Tobacco Review Group, both individual counselling and group therapy increases the chances of quitting. The result of nine studies that were reviewed by the group showed that individual counselling was better than brief advice or usual care. It was also found that group therapy was more effective than self help materials. However, according to two trials reviewed, there was no difference between group therapy and individual therapy <sup>7</sup>(Lancaster, et al. 2000).

### 2.11.2 Pharmacological interventions

In clinical trials, treatment with *Zyban*® (Bupropion) reduced withdrawal symptoms compared to placebo, reduces craving and the urge to smoke, however, the mechanism by which it enhances the ability of participants to abstain from smoking is unknown (GlaxoSmithKline, 2003: 1).

According to the package insert, the side effects of *Zyban*® include:

- General: fever, chest pain, asthenia
- Cardiovascular: tachycardia, postural hypotension, increased blood pressure, flushing, syncope
- Central Nervous System: seizures, insomnia, tremor, concentration disturbance, headache, depression, confusion, anxiety, irritability and hostility.
- Endocrine and metabolic: anorexia
- Gastrointestinal: dry mouth, nausea, vomiting, abdominal pain and constipation.
- Skin/ Hypersensitivity: rash, pruritis and sweating. erythema multiforme and Stevens Johnson Syndrome have also been rarely reported.
- Special senses: tinnitus, visual disturbance and taste disorders

According to a French pharmaceutical company, Sanofi-Synthelabo, a new pill called *Rimonabant* claims to help people quit smoking and lose weight at the same time. It works by blocking the circuits in the brain that control the urge to eat and smoke. In one trial, the drug helped people to shed an

average of 9kg in a year and in another it was found to double the chances of smokers successfully quitting (Donaldson, 2004).

The quality of the studies could not be assessed, as the details of the trials have not yet been published. “Although the type of study design and the relatively large sample sizes are promising, the results do not warrant the drugs status of 'super pill' just yet”<sup>2</sup>(Centre for Reviews and Dissemination, 2004).

Anxiety and depression are symptoms of nicotine withdrawal and smoking cessation can precipitate depression. According to Hughes, there is little evidence that anxiolytics aid smoking cessation. Some anti-depressants (bupropion and nortriptyline) can aid smoking cessation. However, it is not clear whether these effects are specific for certain drugs or it has a class effect (referring to all anti-depressants)<sup>5</sup>(Hughes, Stead and Lancaster, 2000).

### 2.11.3 Hypnotherapy

Hypnotherapy can be an effective tool in withdrawal from tobacco use. It was found that three sessions, on days one, three and seven of the actual tobacco withdrawal week, was useful to most participants. These sessions targeted the behaviour patterns associated with smoking and attempted to create new ones (Ross, 2002: 278).

If hypnosis is to be used, the capacity to be hypnotized is an important factor. In hypnotherapy, participants are asked to reduce as many cigarettes as possible twenty-four hours prior to their appointment as this gives an indication to their motivation and willpower (Roet, 1986:220).

## **2.12 Smoking and the law**

In 1999, the Tobacco Products Control Act of 1993 was amended to impose restrictions on who could buy cigarettes, where and how cigarette companies might promote their products. This 1999 amended act went into force in January 2001 and banned smoking in most public places, places of work (however allow for smoking rooms), banned advertising (logos or brand names on clothing or equipment), banned sponsorship of any organized activity (including sports, festivals and exhibitions) or individuals and banned the free distribution of tobacco products. A second Tobacco Products Control Amendment Bill was published in October 2003. This proposes to ban children under 18 from designated smoking areas, impose a R50 000 fine for selling tobacco products to anyone under 18 years of age, force shops to keep tobacco products under the counter and forbids the use of terms such as *light*, *low tar* or *mild* (Boyle, 2004:5).

## 2.13 Smoking and Homoeopathy

According to Vithoukas, the human being is constructed of three basic planes-the mental/spiritual plane, the emotional plane and the physical plane. He also says that a hierarchical relationship exists among these three planes. The most important plane for the organism is the mental – spiritual plane. The next important level is the emotional plane and the final level of importance is the physical level. *“During the process of treatment, if we observe that the disturbance is moving from more important planes to less important ones and from more important and central organs to less important and peripheral ones, then we know a real cure is taking place”* (Vithoukas. 1991:45).

According to Walji and Kingston (1998) addiction is first and foremost psychological. De Schepper (2001) explains how homeopathic remedies improve the patient’s life on all levels and even though changes on the physical level are remarkable, in homeopathy one expects changes on a deeper level, which is the mental-emotional level.

If the two statements above are evaluated, addiction is primarily psychological and homoeopathy aims to treat at this level, therefore homoeopathy is the ideal treatment for participants addicted to tobacco. Smoking does cause many problems at the physical level but there is no use in treating symptoms, where the cause or root is still present. Therefore, the mind set of a person that begins smoking, is far more integral and needs to be considered when treating the addiction, as it is the cause of the problem. Also, the state of mind

that allows a person to maintain the addiction needs to be addressed. This includes the depressive symptoms, which arise on withdrawal of cigarettes, thus causing the patient to revert back to smoking. It was with this line of thought that this research was conducted, aiming to help people quit smoking by amelioration of their mental-emotional withdrawal symptoms with the use of homoeopathic medicine.

## **2.14 Previous homoeopathic studies based on the management of tobacco addiction**

Three homoeopathic studies on tobacco addiction have previously been conducted at the Durban Institute of Technology. De la Rouviere (1996), compared isotherapy to acupuncture treatment. There were two groups of 15 participants each. One group received acupuncture, which was administered by the researcher. The second group received isotherapy, which was prepared and administered by the researcher. The Mann-Whitney U-test was used to compare the values between the groups before and after treatment. The Wilcoxon Signed Rank Test was used to compare the results within each group before and after treatment. There was a significant difference between the number of cigarettes smoked before and after the acupuncture treatment with  $p = 0.000805385$  ( $p < 0.05$ ). There was also a significant difference between the number of cigarettes smoked before and after homoeopathic treatment with  $p = 0.000893013$  ( $p < 0.05$ ). Thus, it was concluded that both groups were effective in smoking cessation, with the isotherapy group

showing a 7% improvement over the acupuncture group. However, the study design was irregular for the following reasons:

1. There was no placebo group and thus no control with which to compare results.
2. There was also no blinding, which would have been possible had the trial been structured in the following way. The researcher could have carried out the case taking, giving of advice and filling in of questionnaires. The isotherapy and acupuncture could have been administered by another homoeopath and acupuncturist respectively. Participants in the acupuncture group should have received acupuncture treatment and placebo homoeopathic (isotherapy) treatment. Those in the isotherapy group should have received isotherapy prepared by another homoeopath and a form of placebo for acupuncture is available, where the needle only pierces the dermis and does not penetrate deep enough to stimulate a point. This method would have avoided any possible bias from the researcher.

Pautz (1998), compared the effectiveness of isotherapy as compared to isotherapy and similimum in tobacco addiction. There were also two groups of 15 participants each. The first group received isotherapy and similimum treatment and the second group received isotherapy and placebo treatment. The Mann-Whitney U-Test was used for inter-group comparisons and the Wilcoxon Signed Rank Test was used for intra-group comparisons. In each case the alpha level was set at 0.05 level of significance for statistical

analysis. The group which received isotherapy and similimum showed a significant difference at the end of the study with  $p = 0.0197$  ( $p < 0.05$ ). The group which received isotherapy and placebo showed no significant difference with  $p = 0.2094$  ( $p > 0.05$ ). The results reflected that homoeopathic similimum together with isotherapy is an aid to help people stop smoking. A critique of this study is that the groups were not compared to a placebo group which would have made the study more significant and valuable.

Hellberg (2001), evaluated the efficacy of an Anti-tobacco® complex in the management of tobacco addiction. The complex consisted of *Avena sativa* D3, *Ignatia amara* D4, *Daphne indica* D6, *Nux vomica* D6, *Caladium seguinum* D60, *Nicotinum* D60 and *Nicotiana tabacum* D60. There were two groups of twenty participants each. One group received the Anti-Tobacco® complex and the other received placebo treatment. The Mann-Whitney U-Test was used for inter-group comparisons and the Wilcoxon signed Rank Test was used for intra-group comparisons. In each case the alpha level was set at 0.05 level of significance for statistical analysis. There was a statistically significant decrease in smoking consumption in the treatment ( $p = 0.002$ ) and placebo ( $p = 0.001$ ) groups. Thus in both groups  $p < 0.05$ . The results indicated that the Anti-Tobacco® complex and placebo both reduced cigarette consumption therefore the remedies in the complex did not necessarily reduce cigarette consumption. The shortcoming in the methodology of this trial was that “additional treatment was dispensed if necessary” which implies that certain participants received extra medication. If a standard dose was given, this discrepancy would not have occurred.

## 2.15 Materia Medica of homoeopathic remedies used in the complex

Caladium seguinum, Nux vomica and Staphysagria delphinium are shown to increase disgust for tobacco (Schroyens, 1998:1691). It is for this reason they have been chosen; as well as the mental states with which they present.

The mind symptoms of the first remedy, Caladium seguinum includes;

*“Irritable and depressed, mental states and headaches of smokers, restless and cannot control himself after smoking, confused and cannot concentrate, easily angered at everything”* (Vermeulen, 2000:318).

The symptoms of Nux vomica includes: *“Causeless anxiety: taciturn, angry and impatient, quarrelsome if disturbed, indisposition to mental exertion, very irritable: sensitive to all impressions.”* This is frequently the first remedy indicated after much dosing. This remedy is used for somebody that indulges in tobacco, opium, and coffee or overindulges in wine (Vermeulen, 2000:1152).

Staphysagria delphinium includes the following symptoms: *“Sad and irritable, moody, depressed and prefers solitude, weakness of memory, sleep greatly disturbed.”* *“Effects of tobacco smoking [excoriated tongue, gastralgia]; and he also cured with it the habit of “swallowing the tobacco smoke”* (Vermeulen, 2000:1465).

According to Kayne (1997), although classical homoeopaths maintain Hahnemann's principles in prescribing only single remedies, due to clinical experience, it has been found that homoeopathic remedies can be mixed together and administered successfully as a complex. Certain French and German products contain as many as 20 different remedies in potencies ranging from 3x to 30CH.

He also explains that complexes are used for three reasons:

1. The homoeopath may be unsure which remedy is appropriate and therefore if a complex is given the chances of a correct prescription is increased.
2. Complexes are used when a patient is suffering from a condition, which has more than one symptom that needs to be treated or the patient has more than one complaint at one time.
3. The final reason is for the sake of convenience, namely to save time and trouble.

Therefore, *Caladium seguinum* 30CH, *Nux vomica* 30CH, and *Staphysagria delphinium* 30CH, were combined and used as a complex. However, the combined effect had to be investigated. At the same time the complex was also compared to similitum treatment.

## 2.16 Other homoeopathic remedies used in the management of tobacco addiction

- **Nicotiana tabacum (Tobacco):** The tincture is made from the fresh leaves of the tobacco plant, which is collected before the flowers are developed (Murphy, 1995:1671). The symptomology of this remedy contains the following:
  1. Nausea which is worse for the smell of tobacco smoke.
  2. Palpitation due to tobacco
  3. Immoderate smoking of cigars causing vertigo.
  4. Constantly recurring, rigid, titanic spasms from excessive use of tobacco
  5. One patient recorded feeling tormented by the smell of tobacco, which seemed to be all through her (Vermeulen, 2000: 1522).

Thus this remedy may have a role to play in the management of tobacco addiction especially for the treatment of nicotine withdrawal symptoms.

- **Nicotinum (Nicotine):** This is an alkaloid from *Nicotiana tabacum*. According to the homoeopathic proving of this remedy, it produces “Great aversion to tobacco and tobacco smoking.” One prover, who was a smoker was unable to smoke more than a few whiffs and another prover who was a non-smoker, could not approach anyone who was smoking. This remedy is especially useful for problems with

respiratory muscles where breathing is difficult and impeded, as experienced by most smokers (Murphy, 1995:1192).

## **2.17 Similimum treatment**

Similimum arises from the fundamental principle of homoeopathy, which states that “Like Cures Like” (Vithoulkas, 1986: 92). Therefore a substance can be used to treat a condition, whose symptomology are similar to those caused by the same substance in healthy people. Homoeopathic provings are conducted to determine the symptoms elicited by various substances on healthy people.

A detailed case history is vital to arrive at the similimum as each person has a characteristic or unique symptom or presentation, which has to be identified and differentiated from common symptoms associated with the condition. A detailed case history was taken for every participant in this trial and a similimum was selected. The researcher was unaware of which participants received similimum and which received placebo.

## **2.18 The placebo effect**

Placebo refers to a medical treatment, which has no specific medicinal activity and is just a dummy. Placebo effect dates back to Hippocrates who observed that certain gravely ill people seemed to recover through sheer “contentment”.

Placebo accounts much of the benefit people get from anti-depressants and all the benefit from antibiotics taken for viral infections, which are not affected by the drugs (Grady, 2004: 10).

Piasecki and Newhouse (2000) report on two studies regarding smoking reduction and the placebo effect. Tate (1994) conducted a clinical research on the role of expectancies in withdrawal symptoms and suggests that instructional-set manipulations may alter behavioural responses. Before quitting, smokers were given varying instructions as to what withdrawal symptoms to expect while taking the “nicotine gum”, while the gum used was actually placebo. Those who were told not to expect many symptoms, reported fewer complaints, than the no-expectancy controls. Another study by Gottlieb (1987) which used the placebo design, found that the belief that one was receiving nicotine gum resulted in fewer withdrawal symptoms and better success during the first week of quitting (Piasecki and Newhouse, 2000: 74-75).

For the purpose of this trial, placebo was used as a control group, to determine the effectiveness of the treatment groups. The trials conducted by Tate and Gottlieb show how placebo treatments produce results due to psychological conditioning of “a pill for every ill”. The fact that the participants in the placebo group receive something could be enough to help them overcome their problem. This then raises an important question; will every placebo group improve to a certain degree and if so, is this an effective means by which to compare a new intervention? How much of placebo

improvement is allowed to approve or disapprove the effectiveness of an intervention?

## **2.19 Measurement Tools**

The Tolerance Dependence Questionnaire (Appendix C) and the Smoking Log Sheets (Appendix F) were used as measurement tools as they were both successfully used in three previous researches and proved to be reliable.

## CHAPTER 3

### MATERIALS AND METHODS

#### **3.1 Advertisements**

Advertisements were placed on the notice boards at the Durban Institute of Technology and other tertiary education institutions, pharmacies, health shops, libraries, local newspapers and notice boards in the greater Durban area.

#### **3.2 Sample size**

A minimum of forty-five participants was required for the study, but provision was made for sixty participants to allow for dropouts. Forty-five was chosen because the minimum number of participants allowed for a single study is 30 participants. However, this research study investigated three different groups which would equate to ten participants per group. The research co-ordinator advised the researcher that ten participants per group was too small and the sample size should be increased to fifteen participants per group. However, due to problems with patient compliance and a limited budget, the request for the reduction of patient numbers to thirty participants was approved.

Statistical analysis was made from all participants who completed the study, i.e. 43 participants.

### **3.3 Selection of Participants**

Volunteering participants were selected for the study, using convenience sampling, based on the inclusion and exclusion criteria as stated below. The participants were randomly divided into three groups of ten participants each, using the following method: A randomization list was drawn up by the Homoeopathic Day Clinic Director, in which numbers 1 to 60 were listed and each number was randomly assigned to one of the following groups “Complex”, “Similimum” or “Placebo”.

### **3.4 Inclusion Criteria**

- Participants had to be willing to quit smoking.
- Participants had to be between the ages of 18 years to 65 years.
- Both sexes were accepted into the study.
- Participants had to be literate in order to fill in the questionnaires.  
(To ensure objectivity and prevent bias, caused by the presence of the researcher, questionnaires were self administered. Thus, the participants had to be literate in order to understand and fill in the questionnaires correctly.)
- Patients were required to stop smoking, but had they continued smoking, they were still included in the trial on condition they continued recording the number of cigarettes smoked daily in the Smoking Log Sheets. (Appendix F)

### **3.5 Exclusion Criteria**

- Pregnant females were excluded.
- Participants could not be on any other treatment/ intervention for smoking cessation.

### **3.6 Preparation of Experimental Medicines**

Natura Homoeopathic Laboratory (a registered homoeopharmaceutical company), Pretoria, South Africa, prepared the complex according to the standards set out in the German Homoeopathic Pharmacopoeia (British Homoeopathic Association, 1991).

- Complex group: Granules were impregnated with the complex (made in 96% alcohol) in a 1% (v/v) by the means of triple impregnation. This means that 100 parts of sucrose granules were moistened evenly with 1 part of dilution (British Homoeopathic Association, 1991:39).
- Similimum group: The similimum granules were obtained from the Homoeopathic Day Clinic and were prepared according to same method stated for the complex group.
- Placebo group: The granules were impregnated by means of triple impregnation with 96% alcohol. This was done so that there was no difference noted in colour, texture or taste between the medicated granules and the placebo granules.

These medicated granules were placed into powders and were dispensed in this form.

### **3.7 Methodology**

When participants called in for an appointment, they were screened according to the inclusion and exclusion criteria. If they qualified to participate, they were given a date for the first consult and were asked to record the number of cigarettes normally smoked, per day, for seven days before attending the first consultation.

At the first consultation, participants received a full explanation of the purpose of the study and the procedures. They were also informed that they might fall into one of the treatment groups or into the placebo group and that there is a 33% possibility of falling into the placebo group.

Participants received a Subject Information Letter (Appendix G) and a Smoking Log Sheet (Appendix F). Participants also entered the recording of the number of cigarettes normally smoked, which they made seven days prior to the first consult, into the Smoking Log Sheet (Appendix F).

In addition, the participant had to complete the following documents:

- Research participant details (Appendix A)
- Informed consent form (Appendix B)
- Tolerance dependence questionnaire (Appendix C)

Then, a full homoeopathic case history was taken (Appendix D) and a

physical examination (Appendix E) was performed.

At the end of each first consult, the researcher assessed the case and arrived at a similimum. The script was then discussed with the clinician on duty who signed off the script. The participants then collected their prescription at the Homoeopathic Day Clinic reception area, where the dispenser on duty dispensed the medication to the respective groups according to the randomization sheet drawn up by the Homoeopathic Day Clinic Director.

All participants received 56 powders each; the treatment received by the placebo group was therefore indistinguishable from the treatment received by the other groups. Each participant received treatment for four weeks (28 days) therefore two powders were to be taken daily, one in the morning and one at night. One group of participants received the complex preparation. All powders contained granules impregnated with the complex preparation. The other group received the similimum treatment. The first three powders contained granules impregnated with similimum treatment and the remainder powders contained unmedicated granules. The placebo group received the same number of identical looking powders as the other two groups, except that they all contained unmedicated granules.

The first follow up took place two weeks after the initial consult and the final consult took place two weeks after the first follow up. The Tolerance Dependence Questionnaire (Appendix C) was completed at the first and last consultation.

It was assumed that the participants, on acceptance into the trial, will comply with the protocol of the trial. Also, as mentioned above, this study also had a follow-up midway between the trial (two weeks after the initial consult) that was specifically included to ensure compliance and to monitor any problems encountered.

### **3.8 Data Collection**

#### **3.8.1 Daily Smoking Log Sheets** (Appendix F)

The data required for this study was the number of cigarettes smoked before and during the treatment. Smoking Log Sheets were used to record the number of cigarettes smoked. The participants therefore began recording the number of cigarettes smoked per day, one week before the first consultation. Upon receiving the Smoking Log Sheets at the first consult, the participants entered the seven day record of the number of cigarettes normally smoked . After receiving their treatment, participants used the Smoking Log Sheets to record the number of cigarettes smoked daily, until the end of the four-week trial period.

#### **3.8.2 Tolerance Dependence Questionnaire** (Appendix C)

The questionnaire (adapted from Goldstein, 1988), which was filled in during consultation one and consultation three, also provided data for statistical

purposes. This questionnaire assessed the patient's perception of their smoking addiction. The lowest possible score for this test is 0 and the highest score is 37. A decrease in the score was the desired effect, after treatment. To evaluate the validity of this questionnaire, the researcher conducted a pilot study consisting of smokers and non-smokers.

### **3.9 Statistical Analysis**

Statistical analysis was conducted using the Spss (Version 9) Software Suite. This statistical software program was manufactured by Spss Inc, 444n. Michigan Avenue, Chicago, Illinois, USA. Various descriptive and inferential statistical techniques were used. The descriptive procedures used were various tables and graphs and a few summary statistics including but not limited to means, proportions and percentages. Inferential statistics included various hypothesis-testing techniques. Due to the size of the samples, namely 15 in each group, non-parametric statistical tests were used. Type 1 error was set at 5% for all tests, or mentioned differently,  $\alpha = 0.05$ . If the P value was reported as less than 0.05 a significant result was to be declared and the null hypothesis was to be rejected.

### **3.9.1 Procedure 1:** (Intra tests for both treatment and placebo groups)

#### **Wilcoxon's Signed Rank Test**

For each type of scale, a Wilcoxon's Signed Rank Test was conducted to test for a significant difference in population means within each group i.e. before and after treatment.

##### i. Hypothesis testing

The null hypothesis  $H_0$ , states that there is no significant difference after the treatment being compared at the  $\alpha=0.05$  level of significance. The alternative hypothesis  $H_1$  states that there is a significant difference after treatment.

##### ii. Decision rule

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

### **3.9.2 Procedure 2:** (Inter tests between all three groups)

#### **Kruskal Wallis Test**

The difference values between all readings within each group i.e.: the difference between the pre-treatment and post-treatment reading was

calculated. This new column of differences within each group was then compared across all groups using the Kruskal Wallis Test. If this test proved significant it would have been followed up by multiple pair wise comparisons of means using either the Mann-Whitney U Test, which would have shown if any of the two treatments performed significantly better than the other.

i. Hypothesis testing

The null hypothesis  $H_0$ , states that there is no significant difference being compared between the groups being compared at the  $\alpha=0.05$  level of significance. The alternative hypothesis  $H_1$ , states that at least two of the groups will differ significantly at the same level of significance.

ii. Decision rule

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

## CHAPTER 4

### RESULTS

#### 4.1 Introduction

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

The Wilcoxon's Signed Rank Test was used to determine if there was a significant difference in population means within each group.

$H_0$ : There is no difference after treatment

$H_1$ : There is a significant difference after treatment

In each case  $\alpha$  was set at 0.05 (specified level of significance).  $H_0$  was rejected if

$p < \alpha$  and vice versa.

The Kruskal-Wallis Test was used to determine if any of the groups were statistically more significant than the other.

$H_0$ : There is no difference between the groups

$H_1$ : There is a significant difference between the groups

In each case  $\alpha$  was set at 0.05 (specified level of significance).  $H_0$  was rejected if

$p < \alpha$  and vice versa.

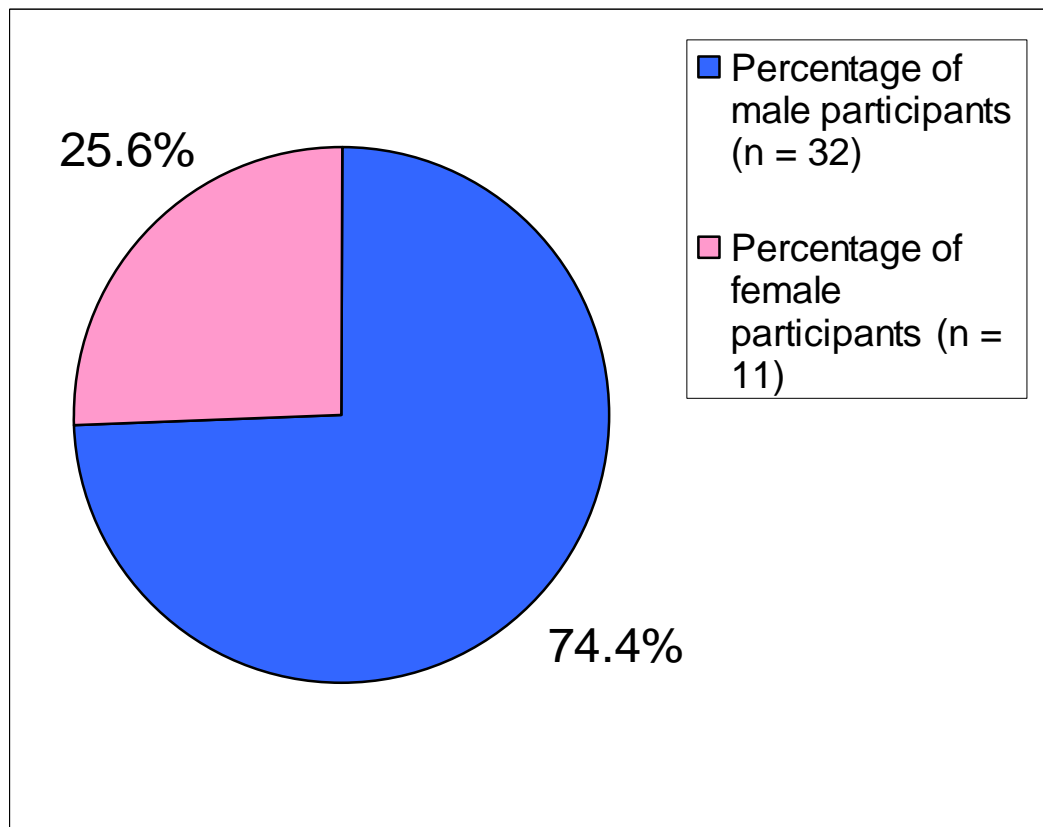
## **4.2 Criteria governing the admissibility of the data**

Only data obtained from the daily smoking log sheets and tolerance dependence questionnaires, which were completed during the trial, were used for statistical analysis. The questionnaires were completed at the first and final consultations. All questionnaires were completed by the participants of the study and were done so in the presence of the researcher.

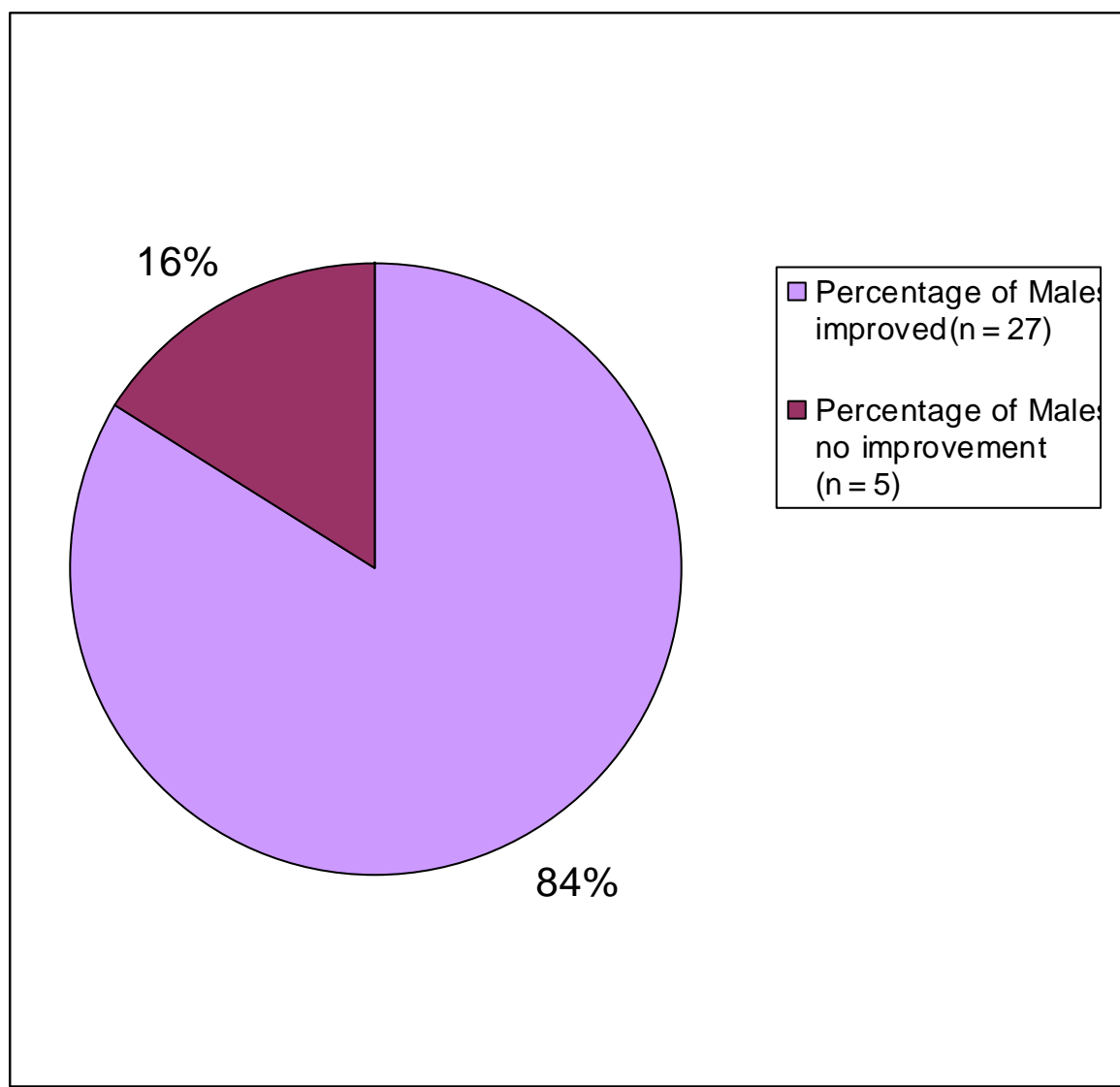
**Table 4.1 Summary data**

	<b>Similimum (n=14)</b>	<b>Complex (n=15)</b>	<b>Placebo (n=14)</b>
<b>% Male (n = 33)</b>	60%	79%	93%
<b>% Female (n = 10)</b>	40%	21%	7%
<b>Average Age</b>	37	40	43
<b>Dependence score (0-37)</b>			
Before treatment (baseline)	23.50	20.86	24.85
After treatment	18.07	15.60	18.93
<b>No. of cigarettes a day</b>			
Before treatment (baseline)	17.79	15.27	15.93
After treatment	13.07	10.87	11.93

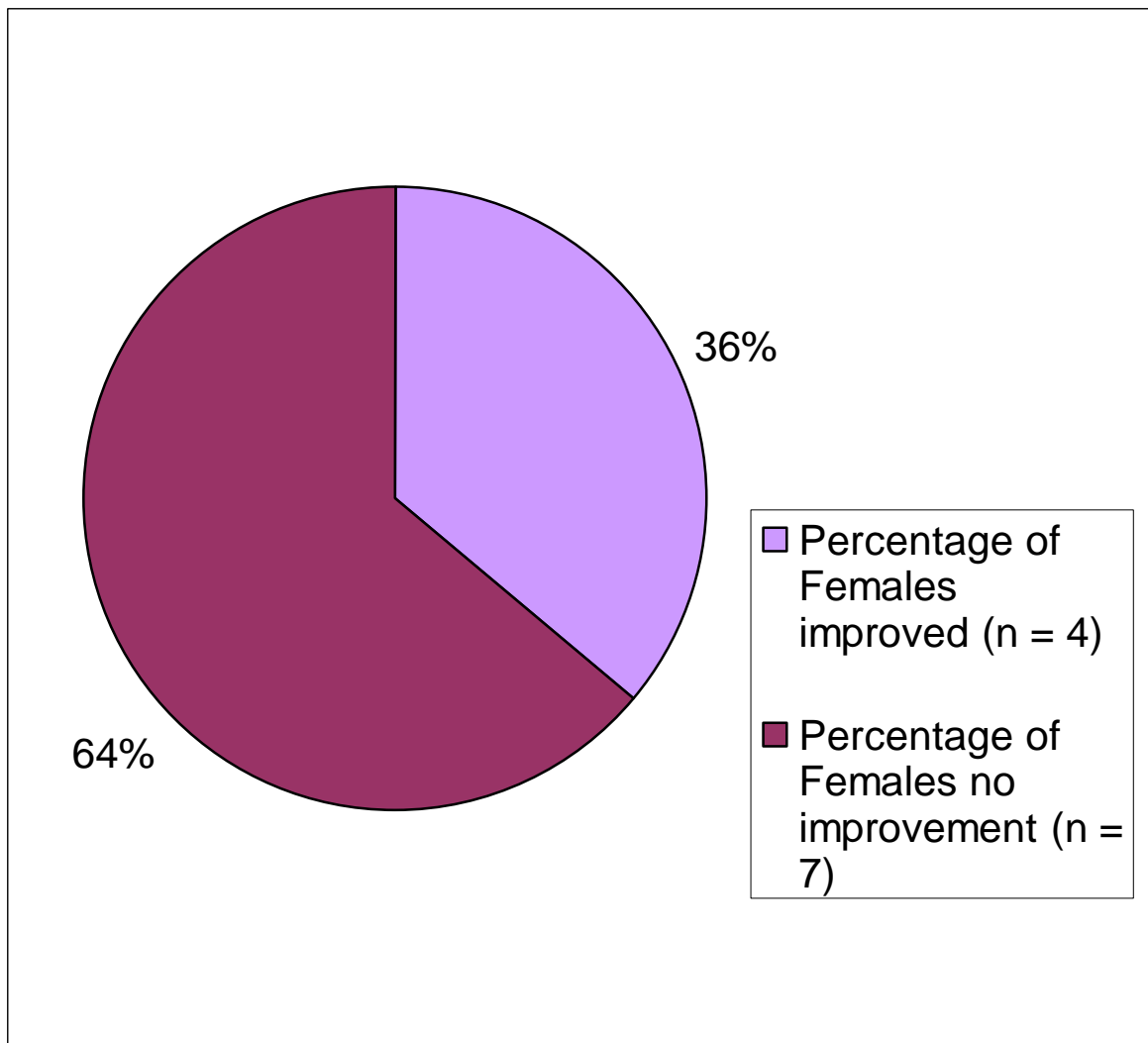
As can be seen from Figure 4.1, more males than females participated in the study. Figures 4.2 and 4.3 show that the rate of improvement amongst males was greater than that amongst females. The improvement was calculated by obtaining the percentage of males and females that showed a reduction in both measurement scales i.e. Tolerance Dependence Questionnaire as well as the Smoking Log Sheets in terms of dependence symptoms and the number of cigarettes smoked.



**Figure 4. 1 Pie-chart showing the percentage of male & female participants**

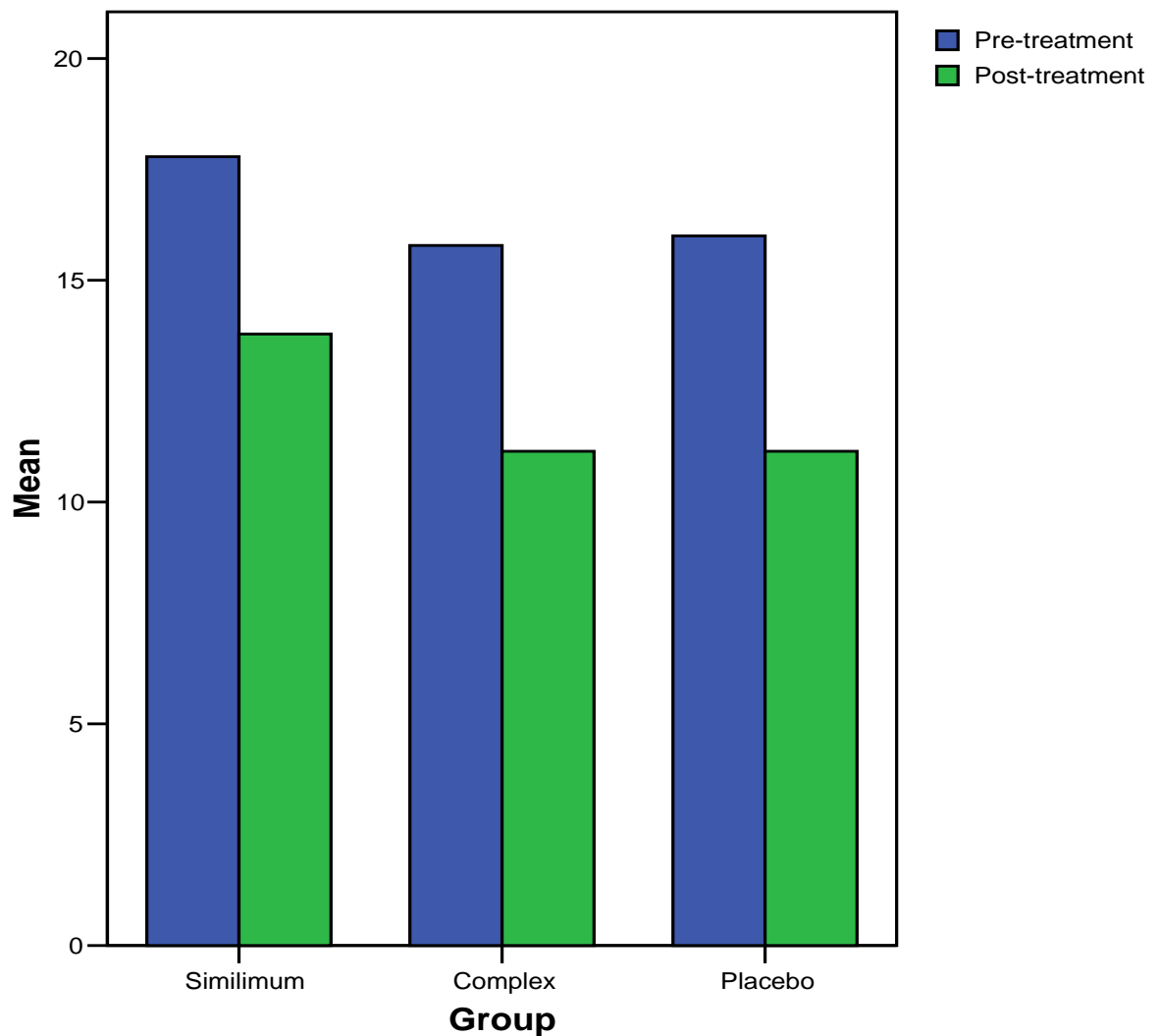


**Figure 4. 2 Pie-chart showing the percentage of improvement in dependence symptoms and number of cigarettes, in male participants, according to the Tolerance Dependence Questionnaire and the Smoking Log Sheets**



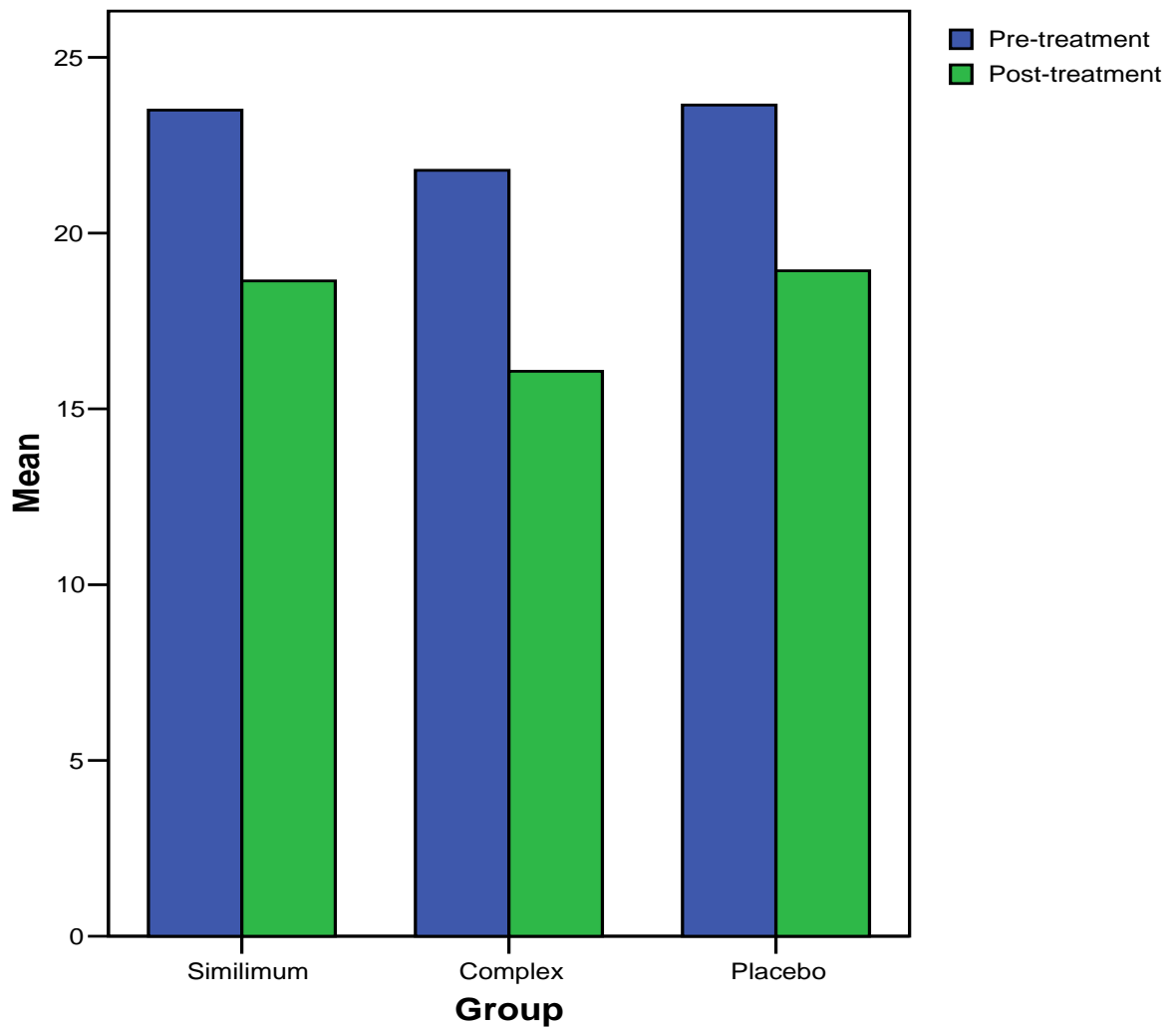
**Figure 4. 3 Pie-chart showing the percentage of improvement in dependence symptoms and number of cigarettes, in female participants, according to the Tolerance Dependence Questionnaire and the Smoking Log Sheets**

Figure 4.4 represents the comparison between the means of Tolerance Dependence Questionnaire values for Group 1 (Similimum), Group 2 (Complex) and Group 3 (Placebo) before and after treatment.



**Figure 4.4 Barchart showing Smoking Log Sheet scores before and after treatment**

Figure 4.5 represents comparisons between the means of Tolerance Dependence Questionnaire values for Group 1 (Similimum), Group 2 (Complex) and Group 3 (Placebo) before and after treatment.



**Figure 4.5 Barchart showing Tolerance Dependence Questionnaire assessments before and after treatment**

## 4.3 Statistical Analysis

### 4.3.1 Comparison within Group 1 (Similimum group) comparing results before and after treatment

**Table 4.2 Group 1 (Similimum group) - Wilcoxon's Signed Rank Test**

	Means		P-value
	Before treatment	After treatment	
<b>Tolerance Dependence Questionnaire</b>	23.50	18.64	<b>0.009</b>
<b>Smoking Log Sheets</b>	17.79	13.79	<b>0.018</b>

The Wilcoxon's Signed Rank Test was used to determine if there was a significant difference in population means within each group i.e. before and after treatment. At the  $\alpha = 0.05$  level of significance, the tests revealed the following:

- For the Tolerance Dependence Questionnaire:

P = 0.009

$\alpha = 0.05$

The P-value < 0.05, therefore the alternate hypothesis was accepted and the null hypothesis was rejected. Thus, there was a statistical difference after treatment.

For the Smoking Log Sheet:

P = 0.018

$\alpha = 0.05$

The P-value < 0.05 therefore the alternate hypothesis was accepted and the null hypothesis was rejected. Thus, there was a statistical difference after treatment.

**4.3.2 Comparison within Group 2 (Complex group) comparing results before and after treatment**

**Table 4.3 Group 2 (Complex group) - Wilcoxon's Signed Ranks Test**

	Means		P-value
	Before treatment	After treatment	
<b>Tolerance Dependence Questionnaire</b>	21.79	16.07	<b>0.005</b>
<b>Smoking Log Sheets</b>	15.79	11.14	<b>0.006</b>

The Wilcoxon's Signed Rank Test was used to determine if there was a significant difference in population means within each group i.e. before and after treatment. At the  $\alpha = 0.05$  level of significance, the tests revealed the following:

For the Tolerance Dependence Questionnaire:

P = 0.005

$\alpha = 0.05$

The P-value < 0.05, therefore the alternate hypothesis was accepted and the null hypothesis was rejected. Thus, there was a statistical difference after treatment.

For the Smoking Log Sheet:

P = 0.006

$\alpha = 0.05$

The P-value < 0.05 therefore the alternate hypothesis was accepted and the null hypothesis was rejected. Thus, there was a statistical difference after treatment.

**4.3.3 Comparison within Group 3 (Placebo group) comparing results before and after treatment**

**Table 4.4 Group 3 (Placebo group) - Wilcoxon's Signed Rank Test**

	Means		P-value
	Before treatment	After treatment	
<b>Tolerance Dependence Questionnaire</b>	<b>23.64</b>	<b>18.93</b>	<b>0.003</b>
<b>Smoking Log Sheets</b>	<b>16.00</b>	<b>11.14</b>	<b>0.001</b>

The Wilcoxon's Signed Rank Test was used to determine if there was a significant difference in population means within each group i.e. before and after treatment. At the  $\alpha = 0.05$  level of significance, the tests revealed the following:

For the Tolerance Dependence Questionnaire:

P = 0.003

$\alpha = 0.05$

The P-value < 0.05, therefore the alternate hypothesis was accepted and the null hypothesis was rejected. Thus, there was a statistical difference after treatment.

For the Smoking Log Sheet:

P = 0.001

$\alpha = 0.05$

The P-value < 0.05 therefore the alternate hypothesis was accepted and the null hypothesis was rejected. Thus, there was a statistical difference after treatment.

#### 4.3.4 COMPARISON BETWEEN GROUPS

**Table 4.5 Kruskal-Wallis Test**

	Means			P-value
	Group 1: Similimum	Group 2: Complex	Group 3: Placebo	
<b>Tolerance Dependence Questionnaire</b>				<b>0.934</b>
Before treatment (Baseline)	23.50	21.79	23.64	
After treatment	18.64	16.07	18.93	
<b>Smoking Log Sheets</b>				<b>0.978</b>
Before treatment (Baseline)	17.79	15.79	16.00	
After treatment	13.79	11.14	12.02	

The Kruskal-Wallis Test was used to determine if any of the groups were statistically more significant than the other. At the  $\alpha = 0.05$  level of significance, the tests revealed the following:

For the Tolerance Dependence Questionnaire:

P = 0.934

$\alpha = 0.05$

The P-value > 0.05, therefore the null hypothesis was accepted and the alternate hypothesis was rejected. Thus, there was no statistical difference between the three groups. The similimum and complex homoeopathic medicines used in this study were not in themselves, effective in improving tolerance dependence symptoms.

For the Smoking Log Sheet:

$P = 0.978$

$\alpha = 0.05$

The P-value  $> 0.05$  therefore the null hypothesis was accepted and the null hypothesis was rejected. Thus, there was no statistical difference between the three groups. The similimum and complex homoeopathic medicines used in the study were not in themselves effective in reducing the amount of cigarettes smoked.

## CHAPTER 5

### DISCUSSION

A statistically significant improvement was demonstrated within all three groups, i.e. similimum, complex and placebo group. However, the comparisons between the groups yielded no significant difference therefore the similimum treatment and the complex did not prove to be effective in the management of tobacco addiction.

The objective of this study was to aid in reduction of withdrawal symptoms, especially the mental symptoms, thus helping people to quit smoking. In terms of this objective, the study was reasonably successful in reducing the subjective withdrawal symptoms, as can be seen from the following extracts:

Complex group:

- Participant 3 reported that there was an improvement in temperament as well as an improvement in athletic performance.
- Participant 4 quit smoking and reported as follows: “There is no craving. It’s rained and the clouds have cleared away.” The participant also reported that he was full of energy and wanted to exercise.
- Participant 7 reported not having any symptoms, even on days he smoked the least, and also stated that smoking was now a habit and was not due to the craving for cigarettes. “This treatment was better than the nicotine patches and gum that was tried before.”

- Participant 14 reduced his smoking from 15-20 per day to 2 per day. He managed to cut out the morning cigarette which he rated as the most difficult to give up at the initial consult and there was drastic improvement in energy which resulted in this participant joining the gym and running every afternoon.
- Participant 17: "I used to get very irritable when I don't get a cigarette, but not now. I don't have cravings, it's a bad habit."

#### Similimum group:

- Participant 13: Reported feeling relaxed despite many stressful circumstances. Before the treatment the participant would have to smoke within five minutes of waking in the morning but after the treatment stated that "the morning cigarette is not a necessity"
- Participant 16: Before the treatment, the participant had difficulty falling asleep and had to smoke to fall asleep. The participant also woke at night and had to smoke. At the end of the trial, the participant reported much better sleep. There was no difficulty falling asleep and did not wake during the night either. There was also improvement in energy levels.
- Participant 23: At the end of the trial, "Taste of the cigarette is now bad." And the patient stopped consuming alcohol after treatment.

#### Placebo group:

- Participant 15: Reported very little withdrawal, "Now and then" but there was definitely a lot of restlessness.

- Participant 19: No change in energy and edgy due to stress. “If I don’t see the cigarette, I don’t worry”
- Participant 25: Improvement in energy and appetite but craving still present.

According to the statistics, the placebo group in this trial did show an improvement. Addiction has been referred to as psychological by Walji and Kingston (1998) and it could be due to willpower that an improvement was noted in certain participants of the placebo group. However, it can be argued that all participants in the study had to be willing to quit smoking therefore they all should have quit. Every individual has a different amount of willpower and it is possible that those that managed to quit had more willpower and thus placebo treatment was sufficient to help with the problem. Further, the Subject Information Letter (Appendix G) expounded the benefits of quitting smoking. This information could have also had an impact on the conscious effort to quit smoking. For future studies, such literature should be excluded from the Subject Information Letter.

The case-taking was thorough and lasted for 45 minutes to an hour. It allowed many to express negative emotions and feel better at the end of the consult. This process could have been therapeutic in itself to help participants thus showing an improvement in the placebo group.

## 5.1 Problems encountered during this trial

Viewing the results of this trial retrospectively some aspects of the research method could have been refined to allow a more positive outcome. An average number of cigarettes smoked during the entire 28 days was used for statistical purposes. Although many participants showed a reduction midway or even near the end of the trial, this was not visible in the statistics due to the number of cigarettes smoked before a reduction occurred. For future trials the first average should be taken before the treatment is administered and a second average should be taken from the time of change in smoking patterns till the end of the study.

Many participants have been smoking for many years. According to this trial, 22 years is the average number of years that participants have smoked cigarettes. Therefore their addiction is longstanding and of a chronic nature thus requiring treatment over a longer time period. It was also noted that three participants quit smoking after the 28 day duration of the trial, therefore the duration of this trial was too short and future trials should be carried out over a longer period to allow the trial medication to have a longer period of time to act on the participant. Perhaps a three month follow-up consultation should be considered for future trials to see if participants had quit smoking, as well as to check if those that had quit smoking had maintained their abstinence.

Similimum prescription was also challenging as thorough case-taking, which is integral in arriving to similimum treatment, was impeded by participants who

did not wish to go into necessary areas such as reasons for maintaining the addiction, reasons for starting smoking as well as the mental-emotional symptomology.

The problem encountered with the Smoking Log Sheets was that an average of cigarettes smoked during the entire 28 days, was taken and even though many participants showed a reduction midway or even near the end of the trial, this was not reflected accurately and was overshadowed by the number of cigarettes smoked before the reduction occurred. Another problem encountered with the trial was that participants came into the research wanting a “miracle pill” that would “make them stop smoking”.

It must be noted that the first and last inclusion criteria contradicted each other in terms of participant compliance. This could have confused the participants and led to inconsistent recording of information.

A clinical trial method that is worth considering in the future is the crossover design which is defined as a repeated measures design which is used to control order effects when comparing two treatments, where half the sample receives treatment A first followed by treatment B, and the other half receives treatment B first followed by treatment A (Portney and Watkins, 1993: 681).

A crossover design uses participants as their own controls rather than using a separate control group. Fewer participants are required as the within-subject variation is less than the between-subject variation. This method is useful in

chronic conditions where the treatment effects are not long lasting and assures that an effect due to the order of treatment is eliminated from the observed treatment effect. Results obtained from a study conducted in this manner improves accuracy of results and should be considered for future trials (Monsen, 1992: 18).

## CHAPTER 6

### CONCLUSION AND RECOMMENDATIONS

#### 6.1 CONCLUSION

It is concluded that in this placebo controlled study, the complex, comprising Caladium seguinum 30CH, Nux vomica 30CH and Staphysagria delphinium 30CH, and similimum treatment was found to be not effective in the management of tobacco addiction.

#### 6.2 RECOMMENDATIONS

- The referral to complex in all the recommendations below refers to the complex used in this study.
1. The trial should be conducted over a longer period to adequately assess the action of the medication over a chronic condition like tobacco addiction as well as to assess the lasting action of the medication.
  2. A trial comparing the effectiveness of the complex alone as a treatment as opposed to the combination of complex and similimum.
  3. Comparison of the use of the complex in different age groups as well as a comparison of the genders.

4. A trial comparing the efficacy of the complex to similimum treatment in pregnant women.
5. A group study where one researcher compares the effectiveness of the nicotine gum and nicotine inhaler to the complex, and the other researcher compares similimum treatment to the above-mentioned forms of nicotine replacement therapy. The researchers can share the groups using nicotine replacement therapy.
6. This study should be repeated with larger numbers, using the double-blind crossover methodology.

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# APPENDICES

## APPENDIX A:

### RESEARCH PATIENT DETAILS

#### PRIVATE AND CONFIDENTIAL

Title: \_\_\_\_\_ Name : \_\_\_\_\_ Surname: \_\_\_\_\_

Date of birth: \_\_\_\_\_ Gender: \_\_\_\_\_

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

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

\_\_\_\_\_ Code: \_\_\_\_\_

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

\_\_\_\_\_ Code: \_\_\_\_\_

Tel.(H): \_\_\_\_\_ Tel.(W): \_\_\_\_\_ Cell-phone: \_\_\_\_\_

#### MEDICAL HISTORY:

Operations: \_\_\_\_\_

\_\_\_\_\_

Serious Illnesses: \_\_\_\_\_

\_\_\_\_\_

Current Medication: (Other homoeopathic medicine, vitamins, contraceptives)

\_\_\_\_\_

\_\_\_\_\_

## APPENDIX B:

### INFORMED CONSENT FORM:

(To be completed in duplicate by patient)

TITLE OF RESEARCH PROJECT:

A placebo controlled study determining the effectiveness of a homoeopathic complex (Caladium sequinum 30CH, Nux vomica 30CH and Staphysagria delphinium 30CH) as compared with homoeopathic similimum treatment in the management of tobacco addiction.

NAME OF SUPERVISOR: Dr. M. Maharaj (M.Tech: Hom)

NAME OF CO-SUPERVISOR: Dr. I. Couchman (M.Tech: Hom)

DATE OF FIRST APPOINTMENT: \_\_\_\_\_

PLEASE CIRCLE THE APPROPRIATE ANSWER:

1. Have you read the research information sheet? YES/NO
2. Have you had the opportunity to ask questions regarding this study? YES/NO
3. Have you received satisfactory answers to your questions? YES/NO
4. Have you had the opportunity to discuss this study? YES/NO
5. Have you received enough information about this study? YES/NO
6. Who have you spoken to? \_\_\_\_\_
7. Do you understand the implications of your involvement in this study? YES/NO
8. Do you understand that you are free to withdraw from this study? YES/NO
  - a) at any time, and
  - b) without having to give reasons for withdrawing
9. Do you agree to voluntarily participate in this study? YES/NO
10. Do you understand that you may receive a placebo during the study? YES/NO
11. Do you understand the difference between a placebo and homoeopathic treatment? YES/NO
12. If you have answered "No" to any of the above questions please obtain the information before signing.

PATIENT NAME: \_\_\_\_\_ SIGNATURE: \_\_\_\_\_

WITNESS NAME : \_\_\_\_\_ SIGNATURE: \_\_\_\_\_

RESEARCH STUDENT: Sapna Lutchman-Maharaj SIGNATURE: \_\_\_\_\_

## APPENDIX C:

### TOLERANCE DEPENDENCE QUESTIONNAIRE:

(Adapted from Goldstein 1988: 11 – 7)

DIRECTIONS: Tick the box of the answer that you find most appropriate for each question.

1. How many cigarettes do you normally smoke per day?
  - 37 or more
  - 27 - 36
  - 17 - 26
  - 7 - 16
  - 6 or less
  
2. When stressed how many cigarettes do you smoke per day?
  - 37 or more
  - 27 - 36
  - 17 - 26
  - 7 - 16
  - 6 or less
  
3. Normally, how often do you have to smoke?
  - Every 10 minutes or less
  - Every 15 minutes
  - Every half hour
  - Every 1 hour to 1½ hours
  - Every 2 – 3 hours
  - Every 4 hours / more
  
4. Do you ever smoke one cigarette immediately after another?
  - Always
  - Frequently
  - Occasionally
  - Seldom
  - Never
  
5. Which cigarette of the day is the most difficult to give up?
  - The cigarette of the morning
  - Midmorning
  - Midday
  - Mid-afternoon
  - Night
  - Any other

6. How soon after you wake up do you smoke your first cigarette?
- Within 5 minutes
  - 6-30 minutes
  - 31-60 minutes
  - 61- or more
7. Do you smoke more frequently during the first hours after waking than during the rest of the day?
- Always
  - Frequently
  - Occasionally
  - Seldom
  - Never
8. Do you find it difficult to refrain from smoking in public places where it is forbidden (for example in church, cinema, library etc.)?
- Always
  - Frequently
  - Occasionally
  - Seldom
  - Never
9. How badly do you want to quit smoking?
- Desperately
  - Very keen
  - Moderately keen
  - Not so serious
  - Do not wish to quit

**APPENDIX D:**

**CASE HISTORY:**

Surname: \_\_\_\_\_  
First name/s: \_\_\_\_\_  
Address: \_\_\_\_\_

Date: \_\_\_\_\_  
M: S: W: D  
Children: \_\_\_\_\_

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

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

Referred by: \_\_\_\_\_

Presenting complaints:

Past medical history and treatment:

Childhood development / milestones:

Allergies:

Vaccination history:

Family medical history:

Any drugs being used presently:

G.I.T:

Desire:

Aversions:

Appetite:

Thirst:

Bowels:

Perspiration:

Energy:

Alcohol:

Smoking:

- How many years have you been smoking for?
- Why do you want to quit smoking? (social pressure, financial, health)
- Do you smoke out of habit or because you crave it?
- Have you ever tried to quit smoking before?
- Were any of the attempts to quit smoking successful? If yes for how long was it effective?

Weather modalities:

Sleep:

Dreams:

Head:

Eyes:

U.R.I & E.N.T:

Ears:

Nose:

Teeth:

Throat:

Chest:

Heart:

Musculo – skeletal:

Skin:

Hair:

Nails:

Urine:

Female: Menses:

Leucorrhoea:

Male: Prostate:

Libido:

Infections:

S.T.D:

Mental:

**APPENDIX E :**

**PHYSICAL EXAMINATION:**

**VITAL SIGNS:**

Temperature: \_\_\_\_\_

Pulse rate: \_\_\_\_\_

Respiratory rate: \_\_\_\_\_

Blood pressure: \_\_\_\_\_

Height: \_\_\_\_\_

Weight: \_\_\_\_\_

**GENERAL EXAMINATION:**

Jaundice/ Anaemia/ Cyanosis/ Clubbing/ Dehydration/ Oedema/  
Lymphadenopathy

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**E.N.T:**

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**CHEST EXAMINATION:**

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**ABDOMINAL EXAMINATION:**

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**APPENDIX F:**

**SMOKING LOG SHEET:**

**RECORDING BEFORE TREATMENT:**

DAY	1	2	3	4	5	6	7
NO. OF CIGARETTES SMOKED							

**RECORDING AFTER TREATMENT:**

DAY:	NO. OF CIGARETTES SMOKED
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	

DAY:	NO. OF CIGARETTES SMOKED
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	
26	
27	
28	

**APPENDIX G:**  
**SUBJECT INFORMATION LETTER:**  
**TITLE OF RESEARCH PROJECT:**

A placebo controlled study determining the effectiveness of a homoeopathic complex (Caladium seguinum 30CH, Nux vomica 30CH and Staphysagria delphinium 30CH) as compared with homoeopathic similimum treatment in the management of tobacco addiction.

**NAME OF SUPERVISOR:** Dr. M. Maharaj (M.Tech: Hom)

**NAME OF CO-SUPERVISOR:** Dr. I. Couchman (M.Tech: Hom)

**NAME OF RESEARCHER:** Sapna Lutchman

**DEAR PARTICIPANT**

**People who stop smoking can live a lot longer; regardless of the age at which they quit according to report in The American Journal of Public Health. The study found that younger people benefit the most but even those who are 65 can add years to their life by quitting.**

**PURPOSE OF THE STUDY:**

This study aims to compare two treatments to see which one is more effective in helping people to stop smoking. The one treatment is a homoeopathic complex and the other treatment is individualised homoeopathic treatment where each person is treated individually.

**PLACEBO:**

One group will receive placebos (powders that don't have the remedy in them). There is a 33% chance of falling into the placebo group. All participants are entitled to free treatment after the study. The treatment offered will depend on the results of the study. The researcher does not know who will receive the actual remedy and who will receive the placebos and will therefore treat all participants as though they were receiving the remedy. This will only be revealed at the end of the trial. This is an important process of the study, as the researcher needs to be able to compare results without bias.

**CONFIDENTIALITY:**

Your privacy will be respected and protected. Only the supervisor will be aware of your identity and all information will be treated with the strictest confidentiality.

Participants will be able to withdraw voluntarily at any stage.

**RECORDING:**

You will be given a smoking log sheet to record the number of cigarettes smoked daily for 7 days before receiving treatment. After receiving medication you are to continue the recording the number of cigarettes smoked per day.

**TAKING YOUR REMEDIES:**

You will receive 56 powders. Take one powder twice a day for four weeks (28 days).

**BENEFITS OF QUITTING:**

- Quitting smoking benefits health no matter at what age one quits.
- Within 24 hours of quitting the blood stream is free of nicotine.
- Within 4 days the body is free of nicotine.
- One year after quitting, the risk of heart disease is halved and within 5 years the risk is almost the same as if you never smoked.
- The risk of cancer, lung disease and stroke also reduces.
- Money saved for a pack a day smoker is over R4000 per year (in 2002)
- Food tastes better, clothes don't stink and breath does not smell disgusting.
- Children benefit when parents stop smoking.

**INCLUSION CRITERIA:**

- Patients must be willing to quit smoking.
- Patients must be between the ages of 18 years to 65 years.
- Both sexes will be accepted
- Patients must be literate in order to be able to fill in the questionnaires.
- Patients will be required to stop smoking but should they continue smoking they will still be included the trial on condition they continue to record the number of cigarettes smoked daily in the smoking log sheets. (Appendix F)

**EXCLUSION CRITERIA:**

- Patients must not be on any other treatment/ intervention for smoking cessation.
- Pregnant females will be excluded.

**Researcher's signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Supervisor's signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Contact phone numbers: Researcher: 083 348 9072**

**Supervisor: Homoeopathic Day Clinic: (031) 204 2041**