An Evaluation Of The Efficacy Of A Homoeopathic Complex Remedy In The Management Of Cigarette Addiction

by

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I, Nicolette Liesel Hellberg do declare that this dissertation is representative of my own work

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This dissertation is dedicated to my parents for their guidance, endless love and support throughout my studies.

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ABSTRACT

The purpose of this double blind placebo controlled study was to evaluate the efficacy of a homoeopathic complex (*Avena sativa* D3, *Ignatia amara* D4, *Daphne indica* D6, *Nux vomica* D6, *Caladium seguinum* D60, *Nicotinum* D60 and *Nicotiana tabacum* D60) in helping people to stop smoking with reference to the Goldstein typology of cigarette smokers in terms of the number of cigarettes smoked per day.

This double blind placebo-controlled study took place at the Technikon Natal Homoeopathic Day Clinic in Durban, South Africa. Thirty participants completed the study.

The treatment group received the Anti-Tobacco® complex in 20% alcohol and the placebo group received 20% alcohol only. Each participant received five treatments over a period of four weeks. Cigarette consumption was recorded daily by each participant and questionnaires were completed on the first and last consultation in the presence of the researcher. The scores of the daily smoking log sheets and questionnaires were totalled and statistically analysed by means of the Mann-Whitney U-test and the Wilcoxon signed ranked test. In each case α was set at 0.05/2 specified level of significance. The null hypothesis was accepted if $p > \alpha/2$ and it was rejected if $p < \alpha/2$.

The results of this investigation indicate that both the Anti-Tobacco® complex and placebo have a statistically significant impact on reduction of cigarette consumption. The homoeopathic remedies in the Anti Tobacco® complex therefore do not necessarily reduce cigarette consumption.

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DEFINITION OF TERMS

Addiction - The state of being given up to some habit, especially strong dependence on a drug (Dorlands 1994).

Placebo - Any dummy medical treatment, originally, a medicinal preparation having no specific pharmacological activity against the patients illness or complaint given solely for the psychophysiological effects of the treatment; more recently, a dummy treatment administered to the control group in a clinical trial in order that the specific and nonspecific effects of the experimental treatment can be distinguished - i.e. the experimental treatment must produce better results than the placebo in order to be considered effective (Dorlands 1994).

Homoeopathy - Homoeopathy is based on the observed biological fact that a diseased deviation from an organism's bioenergetic mean, within reversible limits, can predictably be restored to normal by specially-prepared medicinal stimuli, that need only be administered in small doses, or more often in sub-physiological deconcentrations, owing to an altered receptivity of tissues to such stimuli in disease, provided always (a) that in healthy organism the medicinal agents

chosen would produce symptoms and clinical features like those of the disease, and (b) that obstacles to cure have been removed (Gaier 1991:274).

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

CHAPTER ONE

INTRODUCTION

Smoking is the chief avoidable cause of premature death and ill health in the world. The World Health Organisation (WHO) estimates there are 3 million deaths from smoking every year and if smoking patterns persist, tobacco will kill 10 million smokers every year. (Lindsay and Gaw, 1997.)

One third of the global adult population smokes - the WHO estimates there are about 1100 million smokers in the world. The majority of these (800 million) are in developing countries like South Africa and most of these (700 million) are men (Okeyo, 1998). An estimated 4 million people will die this year from tobacco-related illness, and according to Shaw et al. (2000), each cigarette smoked reduces one's life by 11 minutes. According to the pamphlet *Choices about Smoking, Your health and TB* of the Department of Health (nd: 5), in developing countries cigarette smoking kills more people than acquired immunodeficiency syndrome (AIDS), alcohol, heroin, cocaine and motorcar accidents put together.

According to the pamphlet *Tobacco control in South Africa: The Key Issues* of the National Council Against Smoking (nd: 2), smoking is a leading cause of preventable death and a major drain on the South African economy. The pamphlet states that at present 31% of adults smoke, and that tobacco related diseases kill over 25 000 South Africans each year. Eberman et al. (1998) point out that debilitating disease strikes up to half of all long-term smokers.

Governments are raising large sums of money by means of tobacco taxes, which is, cited by Peters (2000), estimated at R10 billion per annum in South Africa. The tobacco industry spends billions of dollars on advertising and promotions specifically in countries where these practices are not restricted or banned. Thus, the financial aspects associated with the tobacco industry have been a powerful tool in limiting the effect of the knowledge gained by the scientific community regarding the health risks of smoking. (Hurt and Robertson, 1998.)

Tobacco litigation has forced tobacco companies to sit at the bargaining table with tobacco control advocates and has produced settlements which the industry is committed to paying about $10bn each year to reimburse American states for health care expenditure caused by tobacco. This has generally put the industry on the political defensive. (Daynard, et al. 2000.)

Orthodox medical practitioners offer Nicotine Replacement Therapy (NRT) and anti-depressant drugs, except in special circumstances where they use multiple sessions of problem solving and social support counselling, to those individuals who want to give up smoking. Tang et al. (1994) states that NRT and anti-depressant drugs have many side effects with Holzman (1999) stating that there is a possibility that a patient on NRT may become addicted to the nicotine delivery device.

Labadie et al. (1983) studied homoeopathy as an adjunct therapy to tranquilizers and acupuncture treatment. Evaluation of homoeopathic

remedies in management of cigarette addiction has been recorded in two further studies. De la Rouviere (1996) evaluated the efficacy of acupuncture and homoeopathic treatment in helping people to stop smoking, After three months of commencing treatment, the cessation rate of the homoeopathic group was 40% and that of the acupuncture group was 33%. Pautz (1998) evaluated the efficacy of isotherapy and similimum in the management cigarette addiction. After treatment the mean daily consumption of cigarettes decreased by 80.22% in the similimum and isotherapy group and by 51.55% in the isotherapy only group.

According to Lee (1992) homoeopathy increases addict's ability to succeed in breaking the habit and helps them to come to terms with the underlying cause.

The homoeopathic complex that was used in this study is presently marketed as an Over The Counter (OTC) product and is prepared by Natura Homoeopathic Laboratory, Pretoria, South Africa. The product is called Anti-Tobacco®. This complex has not. to date, undergone any clinical trials as to its efficacy in the management of cigarette addiction (Stoffberg, 1999).

The complex is prepared according to Method 5a as stated in the German Homoeopathic Pharmacopoeia (GHP)(1993). The studies done by de la Rouviere (1996) and Pautz (1998) made use of homoeopathic remedies that are only obtainable with a homoeopathic prescription and therefore are not available to the public without consultation and or prescription.

The OTC Anti-Tobacco® complex is stocked by most pharmacies and health shops and is therefore easily accessible to the general public. The complex is relatively cheap (approximately R30), as compared to NRT's, and has no reported side effects or contra-indications.

Therefore the main purpose of this study was to establish the effectiveness of the Anti-Tobacco® complex in the management of cigarette addiction.

CHAPTER TWO

REVIEW OF THE RELATED LITERATURE

2.1 Historical perspective on smoking

Nicotiana tabacum received its specific name from Jean Nicot, French ambassador to Portugal, who introduced the tobacco plant into France about 1560. When Columbus and his followers landed in Cuba in 1492 the practice of smoking tobacco was in common use among the natives throughout the island as well as throughout the continent of America. On their return to Spain, the practice rapidly spread throughout the Peninsula. Sir Walter Raleigh and his companions introduced the practice into England in 1586. From that time the cultivation, manufacture and use of tobacco, either by smoking, snuffing or chewing, rapidly became popular. (Murphy, 1995:1671.)

Cigarettes, as we know them, were introduced in the late 19th century and by the turn of the 20th century largely replaced other forms of tobacco use such as snuff, chewing tobacco and cigars. The introduction of cigarettes is important from the point of view of health because unlike other previous forms of tobacco use, the cigarette smoke is inhaled. Cigarettes are also portable and tobacco smoking became a social and everyday phenomenon rather than performing a ceremonial and formal function. (Lindsay and Gaw, 1997.)

2.2 Smoking Constituents

Cigarette smoke contains more than 4700 chemical compounds including at least 43 cancer-causing substances (Bartecchi, 1995). In the USA, the Environmental Protection Agency (1992) has classified tobacco as a class A carcinogen, along with asbestos, arsenic and randon gas (Lindsay and Gaw, 1992). According to Bittoun (1995) the substances most dangerous in cigarette smoke are carbon monoxide, tar and nicotine. Other poisons in tobacco smoke include formaldehyde, ammonia and benzene.

2.3 Smoking and Addiction

Patients recovering from alcohol, heroin, cocaine, or other dependencies say that quitting smoking is much harder with tobacco relapse rates being higher. Most successful quitters have made five or more serious attempts to stop smoking. (Eberman, et al. 1998.)

Tobacco use reflects a complex interplay of pharmacological, psychological, and socio-economic factors (Clarke, 1998) and should be treated as a form of addiction (Kmietowicz, 2000).

A diagnosis of tobacco dependence can be made by using the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV) (1994:243), when three or more of the identifiers of dependence are present. These include tolerance, withdrawal, use for a longer period than intended, multiple unsuccessful attempts to quit, activities given up or reduced because of substance use, and continued use in spite of health and personal

consequences. The vast majority of tobacco users recognise the signs of dependence. (Eberman, et al. 1998.)

2.4 Smoking and Alcohol

Smoking is often associated with hazardous and harmful alcohol use which, according to Jorm et al. (1999), may reflect a general predisposition to substance abuse. Alcohol consumption has a direct effect on cigarette craving. This is a pharmacological rather than an expectancy influence as the effect was obtained relative to control subjects who had believed that they had consumed alcohol. Therefore, smokers attempting to quit may find a combination of smoking cues and alcohol presenting a strong threat to their continual abstinence. (Burton and Tiffinay, 1997.) Alcohol can cause a relapse and a patient who is quitting smoking, should abstain from alcohol completely (*A US Public Health Services Report*, 2000).

2.5 Smoking, Health and Psychology

2.5.1 Chronic Obstructive Pulmonary Disease

The WHO estimates 600 million people are affected by chronic obstructive pulmonary disease worldwide which kills three million people every year. Experts say that about 60% of those with the condition, known as "smokers lung", continue to smoke and that quitting tobacco is the only intervention that has been shown to halt or slow its progression. (*New hope for chronic smoker*, 2000:4.)

2.5.2 **Pneumococcal Disease**

A study was conducted by Nuorti et al. (2000) who found that cigarette smoking was the strongest independent risk factor for invasive pneumococcal disease among immunocompetent non-elderly adults. This once again illustrates the importance of the prevention and treatment of cigarette smoking addiction.

2.5.3 **Cataract**

Cigarette smoking has been shown to be an important independent risk factor for development of age related cataracts. The risk of cataracts in individuals who quit smoking is uncertain. Some studies have found that risk of cataracts remains elevated for many years following smoking cessation. The Physicians' Health Study 1 (United States of America), based on the first 5 years of follow-up, showed that current smokers of 20 or more cigarettes per day, compared with never smokers, had a 2-fold increased risk of cataracts, while past smokers had a 15% increased risk of cataracts. Mechanisms linking cigarette smoking and cataracts have been described, including a direct effect on the lens, as well as an indirect effect on antioxidant levels and levels of endogenous proteolytic enzymes. These are thought to be important for removal of damaged protein from the lens. Stopping smoking may alleviate further direct damage to lens proteins and, perhaps, allow reversal of some of the early deleterious effects of smoking. (Christen, et al. 2000.)

2.5.4 Arteriosclerosis and Coronary Heart Disease

Both active and passive smoking speed the progression of arteriosclerosis. The effect of smoking on arteriosclerosis may be proportional to the number of cigarettes smoked and the number of years of exposure to tobacco smoke. The impact of smoking is greater among people with diabetes and hypertension. (Wise, 1998.)

Davis (1999) states that patients who smoke or are exposed to Environmental Tobacco Smoke (ETS) have an increased risk of developing coronary heart disease, including stroke, heart attacks, peripheral vascular disease and aortic aneurysms.

2.5.5 Smoking and Pregnancy

In a study conducted by Cnattingius et al. (1999) it was found that smoking was associated with dose dependent increases in the risk of preterm delivery.

2.5.6 Smoking and Hip Fractures

The bone mass of smokers is generally 15-30% lower than that of nonsmokers (Kassier, 2000). Voelker (1999) reports that in a three year Norwegian study researchers found that ex-smokers who had quit five years before still had an increased risk of hip fractures.

2.5.7 **Smoking and Cancer**

Although cigarette smoking is responsible for more than 85% of lung cancers, it has also been associated with cancer of the mouth, pharynx, larynx, oesophagus, stomach, pancreas, uterus, cervix, kidney, ureter, bladder and colon as well as leukaemias. It is also been cited as the leading cause of pulmonary illnesses like, pneumonia, emphysema, bronchitis and influenza. (Bartecchi, et al. 1995.)

Among men in the industrialized countries, smoking is estimated to be the cause of 40-45% of all cancer deaths. Of these cancer associated deaths 90-95% are lung cancer deaths just over 20% are vascular disease deaths, and 35% are cardiovascular disease deaths in those aged 35-69 years. (Okeyo, 1998.)

As much as 90% of all lung cancer is caused by tobacco smoking, including active cigarette smoking, pipe and cigar smoking, and exposure to second-hand smoke (Wingo, et al. 1999).

Smoking also is recognised as a risk factor in cancers of the bladder, larynx, oesophagus and stomach (Sitas, 1998). Frish et al. (1999) found that in women who were smoking tobacco there was a statistically significant association with anal carcinoma.

2.5.8 **Smoking and Hearing Loss**

It was found in a study conducted by Cruickshanks et al. (1998) that men who smoked more than two packs of cigarettes a day were more likely to report a hearing loss than those that did not smoke.

2.5.9 **Smoking and Menopause**

Heavy smokers are known to have lower oestrogen levels and to enter menopause on average one year earlier than non-smokers (Kassier, 2000).

2.5.10 **Smoking and Depression**

Jorm et al. (1999) carried out a survey in Australia by means of questionnaires which showed that smoking is associated with depression and anxiety symptoms. The study demonstrated that depression might play a causal role in smoking indicating an association between smoking and the risk factors for depression. These include being a young adult, having a low occupational status, poor educational or low income, unemployment, divorce or separation, exposure to adverse life events, childhood adversity, and the personality trait of neuroticism and alcohol misuse. An important exception is an individuals sex - women are at higher risk of depression, but not for smoking, although a higher female prevalence of smoking is predicted for the future. (Jorm, et al. 1999.)

Carr (1991) maintains that smokers do not smoke because they enjoy it, but because they are miserable without it. Lang et al. (2000) found in their survey that there was an increase in the depressive symptoms score CES-D

(Center for Epidemiologic Studies-Depression Scale) in people who had stopped smoking. This reinforces the need for social support during this period of smoking cessation.

2.6 Passive Smoking

Passive smoking is the breathing of side stream smoke (emitted from the burning of tobacco between puffs), or of smoke exhaled by the smoker. This possesses a similar health risk to that of smoking. Passive smoke contains more particles of smaller diameter therefore it is more likely to be deposited in the lungs. (Bartecchi, 1995.)

It is estimated that over 20 years, a non-smoker working all day in a room polluted by tobacco smoke is 100 times more likely to contract lung cancer than from working in a building containing asbestos. Exposure to Environmental Tobacco Smoke (ETS) is one of the major causes of lung cancer and in those with long-term exposure, the risk is increased by between 20% to 30%. (*The New Tobacco Law* 2000.)

In the US, ETS exposure causes 3000 deaths due to ischaemic heart disease and 1 900 to 2 700 deaths due to sudden infant death syndrome. ETS is also responsible for 9 700 to 18 600 cases of low birth weight infants annually, 8 000 to 26 000 new cases of asthma in children and 150 000 to 300 000 cases of bronchitis or pneumonia in children aged 18 months and younger (of which 7 500 to 15 000 require hospitalisation). (Davis, 1999.)

Furthermore it was found by Bek et al. (1999) that passive smoking, especially of maternal and paternal origin, has an aversive effect on children's pulmonary function.

Passive smoking is responsible for many children's respiratory diseases like pneumonia, bronchitis and reduced lung function. It has also been shown to play a causal role in glue ear, asthma and wheezing. The unborn child is however most severely affected by passive smoking as they are usually of a very low birthweight. Passive smoking also causes irritation and discomfort, adult asthma and heart disease. (Wald, et al. 1991.)

According to Werner and Pearson (1998) the study by Howard et al. implicates not only active smoking but also ETS as a cause for atherosclerotic progression. This implies that it is an added risk factor in those patients with existing coronary vascular disease, diabetes and hypertension.

2.7 Smoking Intervention

Successful tobacco control is ultimately accomplished through programs directed at individuals, communities and entire countries (Samet, et al. 1998).

The minimum intervention involves effective and efficient use of health professional's time to equip patients with the knowledge and motivation they need to make health enhancing behavioural changes later. The key is

helping the patient to move towards quitting through the understanding of his or her own smoking behaviour. A relevant action plan should then be devised and implemented. (Lindsay and Gaw, 1997.)

A big problem is to keep adolescents from starting to smoke. Present laws make it illegal to sell cigarettes to minors, but more research has to be conducted to prevent adolescents from becoming established smokers. (Emery, et al. 1999.)

Project DARE (Drug Abuse Resistance Education) was originally developed as a joint project of the Los Angeles Police Department and the Los Angeles Unified School District. It is now operated in several hundred communities across the U.S.A. Project DARE is designed to help fifth and six grade students recognise and resist peer pressure that frequently leads to experimentation with alcohol and drugs. (McNee, 1994.)

Since 1996, all participants in the Miss Sweden contest have to be totally smoke free. The finalists then receive special training from the Swedish National Institute of Public Health in Stockholm to enable them to work as anti-tobacco advocates in schools. (Steimle, 1999.)

Most developed countries have banned tobacco advertising completely and cigarette packaging by law is required to have pictures of, for example, hearts, which are damaged due to smoking etc. Health warnings on cigarette packs no longer contain general warnings but tend to be more

specific for example: "SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide". (Randal, 1996.) The Government of Canada recently passed a new regulation requiring tough messages and graphic full-colour images to cover 50% of the cigarette packages (Brundtland, 2000). Some governments have proposed charters to encourage pubs, restaurants and hotels to provide well-ventilated smoking and non-smoking areas. They are also increasing the taxation on tobacco. (Chambers, 1999.)

According to the *Gazetted Regulations in the Tobacco Products Control Amendment Act No.12* of South Africa (1999) it is prohibited to sell cigarettes to minors under the age of 16 years and if shopkeepers are found guilty, they will be convicted. There is now also a ban on tobacco advertising and sponsorships with smoking being restricted in public and work places. Smoking areas of all public places should not exceed 25% of the total floor space. Nicotine and tar levels in cigarettes have also been restricted. This new law comes into effect immediately but businesses have been given until January 1, 2001 to comply with the requirements. (*The New Tobacco Law* 2000.)

Household and workplace smoking restrictions can reduce the opportunity to smoke and thereby interrupt the establishment of nicotine addiction. Results from the national surveys i.e. the association between household and workplace smoking restrictions and adolescent smoking, strongly suggest that smoke-free homes are associated with significantly lower rates of adolescent smoking. Complete rather than partial bans on smoking in the

home and in the workplace produced the most significant associations. (Farkas. et al. 2000.) Although exposure to ETS at the workplace is involuntary, it is easily preventable. The prevention of smoking in the workplace can significantly and rapidly improve the respiratory health of workers (Lam, et al. 2000).

2.8 Smoking and Diet

Smoking has been linked to stress and irritability and damage to the immune system. Therefore recommended nutrients are vitamin C for stress reduction. increased resistance to infection and boosting of the immune system. Anti-oxidants are given to boost the immune system and a vitamin B complex is given to neutralise the free radicals in cigarette smoke. (Walji and Kingston, 1998.)

Balch and Balch (1997:486-487) recommend vitamin C 5,000 - 20,000 mg daily as an antioxidant and to replace the depletion of vitamin C in the body caused by smoking. They also recommend a vitamin B complex (100 mg daily) extra vitamin B12 (1,000 mcg daily), folic acid (400 mcg daily) and vitamin E (200iu daily) for the protection of cells caused by the damage of tobacco smoke. The dietary advice is given as follows: Persons should have a diet rich in fresh and raw vegetables and brightly coloured fruit; they should stay away from any junk food; the diet should also be low in fats and red meat and animal protein except for boiled fish.

It is a well-known fact that most people gain weight after quitting smoking. On average they gain between 2-4 kg most people resuming smoking to get their figure back. One must ask oneself if the health risks of this weight gain outweigh the benefits if quitting smoking. The weight gain is mainly due to the removal of the dietary and metabolic effects of nicotine. Therefore, quitters should be given simple dietary and exercise advice to minimise weight gain. (Mendelsohn, 1999.)

2.9 Allopathic Management of Cigarette Addiction

The Agency for Health Care Policy and Research affirms the need for routine, systematic identification and treatment of tobacco dependence within all healthcare systems. The inquiry about tobacco use needs to become as routine as checking vital signs. (Eberman, et al. 1998.) General practitioners usually offer NRT, except in special circumstances when they use multiple sessions of problem solving and social support counselling (Hughes, et al. 1999). However, NRT is not suitable for all smokers. According to the package insert of "QUIT" (Wrapsa Packaging and Manufacturing (PTY) LTD 1997), NRT is contra indicated in children under the age of 18, people with heart and blood vessel disease and in women who may become pregnant, who are pregnant or are nursing.

The pharmacotherapy used by the allopathic profession in helping people to stop smoking includes OTC NRT's like nicotine gum, patches, inhalers and sprays.

2.9.1 Nicotine Gum

In September 1995 nicotine gum (Nicorette®) became an available OTC drug. In April 1996 nicotine patches (Nicoderm CQ® and Nicotrol®) became available OTC drugs. These two products' OTC availability was justified by the thought that 70% of the smokers who were interested in quitting would most likely not make an appointment to see their physician to obtain NRT. (Tang, et al. 1994.)

The label for the OTC nicotine gum recommends chewing 1 -2 pieces per hour. The 2-mg dosage is to be used for those who smoke fewer than 25 cigarettes per day and the 4-mg dosage is for those who smoke at least 25 cigarettes per day. The label recommends this dosing for 6 weeks followed by 6 weeks of tapering. Side effects of nicotine gum include burning and ulceration of the mouth, throat irritation, dyspepsia, nausea, hiccoughs and temporomandibular arthralgia. (Tang, et al. 1994.)

2.9.2 Nicotine Patch

The Nicotrol® patch label instructs patients to use the patch for 16 hours per day for 6 weeks with no tapering period. The US Food and Drug Administration do not approve the nicotine gum and patch. (Hughes, et al.1999.) Nicotine patches can cause itching, local erythema and insomnia (Tang, et al. 1994).

2.9.3 **Nicotine Nasal Spray**

The nicotine nasal spray (Nicotrol® nasal spray) is a prescription drug designed to deliver nicotine in a more rapid manner, which thereby serves as a better substitute than gum or patch. Smokers use 1 to 2 doses per hour for 3 months. A large majority of smokers experienced nasal and throat irritation, rhinitis, sneezing, coughing, and watering eyes. (Hughes, et al. 1999.) The nicotine nasal spray can also cause blocked nose, nasal blood spotting, nasal ulceration and vomiting (Sutherland, et al. 1992).

2.9.4 **Nicotine Inhaler**

The Nicotine inhaler (Nicotrol® Inhaler) became available as a prescription drug in 1998. It is a plastic rod with a nicotine plug that provides a nicotine vapour when puffed on. The inhaler doubled the quit rates compared with placebo. The major difference of the inhaler with other NRT's is that the inhaler substitutes for some of the behavioural features of smoking. The device does lose significant bioavailability at ambient temperatures below 10°C. Adverse effects consist of mouth and throat irritation and coughing. (Hughes, et al. 1999.)

2.9.5 **Bupropion Hydrochloride**

Bupropion is an atypical antidepressant that has both dopaminergic and adrenergic actions. The slow-release preparation of bupropion hydrochloride became available as a prescription item under a trade name specific for smoking cessation, Zyban®. Smokers who use bupropion hydrochloride must begin the treatment one-week prior to smoking cessation, with the

suggested dosage being 300mg/d and the duration of treatment being 7 to 12 weeks. Adverse effects include a dry mouth and insomnia.The use of bupropion hydrochloride is contra indicated in smokers who have a history of seizures, anorexia, heavy alcohol use, or head trauma. (Hughes, et al. 1999.)

2.9.6 **Second-line Pharmacotherapies**

Clonidine and nortriptyline hydrochlorides are recommended as second-line pharmacotherapies (*A US Public Health Service Report*, 2000). Clonidine hydrochloride is a drug that is used for preventing migraines, other vascular headaches and for menopausal patients on oestrogen or menopausal flushes where oestrogen is contraindicated. This drug has numerous side effects and special precautions. (van Rooyen and Snyman, 1996:27.)

Nortriptyline hydrochloride is used for the treatment of depression with or without anxiety, and has numerous contraindications, side effects, special precautions and drug interactions (van Rooyen and Snyman, 1996:8).

2.10 **Behavioural Therapy and Management of Cigarette Addiction**

All physicians at the Nicotine Dependence Centre of the Mayo Clinic are encouraged to ask their patients about tobacco use. The centre also provides professional, individualised treatment for patients who want or need more assistance. This service is also available to all Mayo Clinic employees and their families. (Eberman, et al.1998.)

The role of the physician can not be underestimated and other help from professionals who have daily contact with the patients can also influence them to cease smoking. Success in breaking the habit depends on both the smoker and the method. Smokers must be committed to stopping in order to succeed, and this commitment is stronger in people who believe that the dangers of smoking are personally relevant. (Lewith, 1995.)

The techniques of motivational interviewing can be helpful in preparing people to change their behaviour. The elements of this approach are to build empathy with the smoker, avoid arguments and support the smoker's autonomy and confidence to make a change. The doctor should acknowledge the patients' ambivalence about quitting and empathise that the decision is theirs, he or she should also be asked to articulate their own reasons for wanting to quit and the barriers that stand in their way. The doctor should help the patient understand the magnitude of their health risk and identify potential solutions to the barriers. It is also the practitioner's responsibility to point out the strengths the patient brings to the task and the progress that they have made so far. It may also be useful to probe into the details of the patients' recent relapse to smoking, to help them learn from past mistakes and how to be more successful in the future. By combining patience and persistence, the practitioner may be able to help the patient to make another attempt to quit in the near future. (Rigotti. 2000.)

According to Muers (1999) the final success rate depends on many variables which include social support, advice and the use of NRT. Muers (1999) also states when all this assistance is available; a success rate of 12% may be possible.

2.11 Cessation of Smoking - Withdrawal Symptoms

Common withdrawal symptoms include a desire to smoke, insomnia, anxiety and inability to concentrate. Physical symptoms include tachycardia, and tremors and restlessness. Studies suggest that immediate total withdrawal from smoking might be a more effective method of smoking cessation than gradual reduction of cigarette consumption (Schiffman and Javik, 1976). The *US Public Health Services Report* (2000) also states that total abstinence is essential after the quit date has been set.

2.12 Negative Effects of Smoking Cessation

2.12.1 Weight Gain

Weight gain on average of between 2-4 kg in smoking cessation occurs because of the removal of dietary and metabolic effects of nicotine (Mendelsohn, 1999).

2.12.2 Depression

It has been shown by Glassmann et al. (1990) that smokers with major depression were less likely to quit smoking, with depression increasing the risk of a patient becoming a smoker.

Clinical depression may follow abrupt nicotine withdrawal. Functional brain imaging research supports this relationship and the use of anti-depressants to treat nicotine dependence emphasizes the overlap between nicotine and depression (Piasecki and Newhouse, 2000).

2.12.3 **Ulcerative Colitis**

Ulcerative colitis is largely a disease of non-smokers and patients with ulcerative colitis who are ex-smokers have usually acquired the disease within a few years after they stopped smoking. Patients reported that when they smoked intermittently they often experienced improvements in their colitis symptoms during the period when they were smoking. Treatment with transdermal nicotine patches and mesalamine (5-aminosalycyclic acid) has a beneficial effect on active colitis. (Thomas, et al. 1995.)

12.2.4 **Parkinson Disease**

Epidemiological studies have shown an inverse relationship between smoking and Parkinson disease and a reduction in nicotine acetylcholine receptors (nAChR) in Parkinson disease, suggesting that nAChR stimulation may be beneficial in this disorder (Piasecki and Newhouse, 2000).

2.13 **Alternative Treatment of Cigarette Addiction**

2.13.1 **Acupuncture**

The endorphins released through the acupuncture–endorphin hypothesis play a role in the treatment or management of the addicts' withdrawal

symptoms. The evidence found suggests that acupuncture is as good as nicotine replacement therapies in aiding smoking cessation. (Lewith, 1995.)

2.13.2 **Hypnosis**

Hypnosis can not reach large numbers of smokers, but it can help some smokers quit, particularly those who have tried other methods and need intensive individual attention to succeed. Hypnosis seems to reach its best success rates when it is combined with other therapies. On its own however, it has been shown to be a good technique to aid in smoking cessation. (Lewith, 1995.)

2.13.3 **Self-help books**

Many people also buy and use self-help books to help them overcome their smoking addiction (Schwartz, 1992).

2.14 **Homoeopathy in the Management of Cigarette Addiction**

Homoeopaths consider health as the experience of wellbeing on the physical, emotional and mental levels. Therefore homoeopathy can be used to help emotional and psychological problems, such as addictions, phobias or obsessive behaviours. (Walji and Kingston, 1998.)

The homoeopathic consultation in itself is therapeutic provided the therapist has a caring, positive warm attitude and does not condone his patient's behaviour (Ledermann, 1995).

According to Lee (1992:17), homoeopathy increases the addict's ability to succeed in breaking his habit, helps him to come to terms with the underlying cause and also helps with the withdrawal symptoms.

Labadie et al. (1983) studied homoeopathy as an adjunct therapy to tranquilizers and acupuncture treatment. Two studies on homoeopathy and tobacco control have been conducted at Technikon Natal. The first study was a clinical trial which compared isotherapy (a form of homoeopathy) and acupuncture. Thirty volunteering participants were randomly divided into the two groups with each participant completing the three-month trial period. Each participant, before the treatments, completed three questionnaires as per Goldstein (1988). Each subject recorded daily cigarette consumption during the three-month period and the mean values were calculated for both the acupuncture group and the homoeopathic group before and after the treatment. The alpha level was set at 0.05 level of significance for the statistical analysis. The Mann-Whitney U-test was used to compare the values between the groups before and after the treatment. The Wilcoxon signed ranks test was used to compare the results within each group before and after the treatment. There was no significant difference in the daily cigarette consumption between the 2 groups. Consequent to the treatment, both the acupuncture and the homoeopathic group were found to show a significant decrease in the number of cigarette smoked. After three months of commencing treatment, the cessation rate of the homoeopathic group was 40% and that of the acupuncture group was 33%. (de la Rouviere, 1996.) Criticism of this study can be made; no placebo was employed, with

no blinding. Blinding was not possible with this, resulting in the researcher possibly exerting an unconscious influence in one direction or another.

In the second study, isotherapy and the homoeopathic similimum was compared to a control group of isotherapy alone. Thirty participants completed the double-blind randomised trial that took place in the northern suburbs of Gauteng. Each participant received 5 treatments over a period of three months. Each participant recorded cigarette consumption daily with questionnaires as per Goldstein (1988) being completed in the presence of the researcher at each consultation. The daily smoking logs and the questionnaire scores were totaled and statistically analysed. Comparisons with respect to cigarette consumption between the two groups were analysed using the two-sample unpaired t-test. The Mann-Whitney U-test was used for inter-group comparisons and the Wilcoxon signed ranks test for intra-group comparison with respect to the questionnaires. In each case α was set at 0.05. There was a significant difference between the experimental and control groups after treatment with regard to cigarette smoke consumption and nicotine tolerance / dependence. Mean daily consumption of cigarettes decreased by 80.22% in the similimum and isotherapy group and by 51.55% in the isotherapy only group. (Pautz, 1998). The critique of this study is that it would have been more valuable if the researcher had compared similimum to a placebo group, and employed a double blind procedure.

The complex evaluated in this study contains *Nicotinum* and *Nicotiana tabacum* and these two remedies are a form of homoeopathic isotherapy, which were both used in the previous two studies.

Homoeopathy can be useful in treating complaints both at the local and constitutional levels which aims to put the individual more in touch with his or her inner resources and potential, that is with the inner strength. This improves the health and well being of people whether suffering from addictions or not. (Gibson, 1994.)

2.14.1 Anti-Tobacco®: Materia medica and potencies

2.14.1.1 *Avena sativa* D3

According to Murphy (1995:214) it is especially useful in the treatment of addictive disorders, such as morphine and tobacco addiction. It appears to produce the same kind of soothing action without creating a habit of its own.

2.14.1.2 *Caladium seguinum* D60

Modifies the craving for tobacco and according to Vermeulen (1997:344), is used for the treatment of a tobacco heart. He also says it is indicated for mental states and headaches of smokers. According to Murphy (1995:310) *Caladium seguinum* is indicated clinically in the tobacco habit and in tobacco poisoning.

2.14.1.3 ***Daphne indica*** D6

This remedy has an incredible craving for tobacco and is also used in the treatment of prostatic discharge, which is aggravated by tobacco (Vermeulen, 1994:675).

2.14.1.4 ***Ignatia amara*** D4

Ignatia amara according to Vermeulen (1994:870-880) has an extreme aversion to tobacco smoke and they are generally aggravated from tobacco smoke. They have nausea from smoking. They can be hysterical, quarrelsome and weepy and have violent mood swings. These are all well-known psychological withdrawal symptoms.

2.14.1.5 ***Nicotiana tabacum*** D60

Nicotiana tabacum is considered a form of isotherapy and is used as an antidote to counter the craving for tobacco when giving up the cigarette habit (Natura Homoeopathic Laboratory, 2000). According to Di Nepi (1990) one can reduce the dosage of conventional medication whilst using isotherapy. According to Vermeulen (1994:1571), *Nicotiana tabacum* is indicated in constantly recurring, rigid, tetanic spasms, which result from the excessive use of tobacco.

2.14.1.6 ***Nicotinum*** D60

Nicotinum is a form of isotherapy. It is also indicated where there is a great aversion to tobacco and tobacco smoking. According to Murphy (1995:1192), one prover, a smoker, was unable to smoke more than a few

puffs, the other a non-smoker, could not approach any one who was smoking. Clinically *Nicotinum* is indicated for effects from tobacco.

2.14.1.7 ***Nux vomica*** D6

This homoeopathic first aid remedy is indicated after much dosing with chemicals of any sort. Vermeulen (1994:1216) states that it establishes a sort of equilibrium of forces, counteracts chronic effects and is used for the treatment of overindulgence in the sedative effect of tobacco. According to Lee (1992:17), *Nux vomica* is recommended for tranquilliser addicts and alcoholics when the underlying cause is tension, pressure or irritability. It is indicated in persons who are angry and always irritable or impatient and for persons who are addicted to wine, coffee, and sedative effects of tobacco. Patients then suffer from ill effects from these the next day by having an irritable temper. It is therefore very much indicated in the treatment of withdrawal symptoms in smoking cessation.

According to Koehler (1983:145) low potency remedies ranging from mother tinctures to a D6, are used in organic diseases. *Avena sativa* appears in a D3, *Ignatia amara* in a D4 and *Daphne indica* and *Nux vomica* appear in a D6 and are therefore mainly indicated in the treatment of the physical effects caused by smoking. *Caladium seguinum*, *Nicotinum* and *Nicotiana tabacum* appear in a D60, which are high potencies (Koehler 1983:145) and are therefore indicated for the treatment of mental and emotional effects of tobacco addiction and withdrawal.

2.15 The Placebo and Hawthorne Effects

The placebo effect is particularly relevant in respect of a homoeopathic trial due to the high level of criticism from other medical and scientific disciplines. It is maintained by these sectors that homoeopathy itself is merely a placebo effect. Apparent improvements in patients receiving placebos can be attributed to spontaneous improvement or self-healing, additional interventions, selective reporting and patient bias. Apparent toxic effects of placebos can be explained as everyday symptoms or symptoms of the disease under study. (Kienle and Kiene, 1998.)

The placebo effect is essential for the methodology of clinical judgement and of clinical research. In other words, the use of a placebo in the double-blind randomised design is known as the gold standard of modern clinical trials. (Kienle and Kiene, 1998.) Up to 33% of the patients on placebo are satisfactorily relieved by placebos alone, this observation was made by Henry K Breecher (1955) in his article "The Powerful Placebo". Since Breechers article, this became a rule: a one third placebo response. A recent article in the Journal of the American Medical Association (JAMA) by Turner et al. (1994) claimed that Breechers one third placebo response was a misconception and that the placebo rate was actually much higher, being up to 70%, 90% and even 100%. The 15 trials that were reviewed by Breecher (1955) were recently reanalysed and it turned out that not a single trial gave the slightest reason to assume the existence of any placebo effect (Kienle, 1997).

According to Terre Blanche and Durrheim (1999) human subjects are not inert and react when being studied. Changes that occur in behaviour can be due to reactions to being studied rather than to the intervention or treatment itself, a well-known demonstration of this includes the experimental or Hawthorne effect.

According to the *US Public Health Services Report* (2000) a physician's advice to quit smoking already increases the abstinence rates significantly. There is also a strong dose-response relationship between the intensity of tobacco dependence counselling and its effectiveness. Treatments involving person-to-person contact (via individuals, group, or proactive telephone counselling) are effective, and their effectiveness increases with treatment intensity (i.e. the session length, number of sessions, and total minutes of contact.)

CHAPTER THREE

MATERIALS AND METHODS

3.1 Advertisements

Advertisements were placed on notice boards at Technikon Natal, M L Sultan Technikon and University of Natal, pharmacies, health shops, local sports clubs, libraries, on notice boards of public places and in local newspapers.

3.2 Sampling Method

Forty volunteering patients participated in this study. The participants were enrolled as they volunteered and were assigned into the treatment group or placebo group by a double blind random sampling technique, described as follows: The word "Treatment " was written on 20 small pieces of paper and the word "Placebo" was written on the remaining 20 small pieces of paper. The 40 pieces of paper were then folded and placed into a suitable receptacle and were drawn out by an independent person. As each paper was drawn out the words "Placebo" or "Treatment" were then written next to the corresponding number.

3.3 Sample Size

A minimum number of 30 participants was needed for this study, but provision was made for 40 patients to allow for dropouts. Statistical analysis was made from the first thirty participants who completed the four-week trial period.

3.4 The Subjects

3.4.1 Inclusion Criteria

- Subjects of both sexes were accepted;
- Subjects had to be over the age of 18 years;
- Subjects had to have been smoking 15 or more cigarettes per day for more than one year;
- Subjects had to be literate to the extent of being able to understand and complete questionnaires.

3.4.2 Exclusion Criteria

- Participants were not to be on any other programs or treatments for smoking cessation, may it be homoeopathic, acupuncture, hypnosis or orthodox.

3.5 Methodology

Patients that were accepted into the study received a full explanation of the purpose of the study and the procedures that followed, which included an explanation that they might fall into the treatment group or into the placebo group.

On their first visit, patients completed the following documentation in the presence of the researcher:

- Research Patient Details (Appendix A)
- Informed consent form (Burger 1999)(Appendix B)

- Questionnaire on Health Hazards of Smoking (Goldstein 1988:2-1 - 2-3) (Appendix C)
- Tolerance Dependence Questionnaire (Goldstein 1988:11-7) (Appendix D)
- and the Questionnaire on Types of Smoking (Goldstein 1988:11-9 - 11-10) (Appendix E).

The researcher then took a medical case history and performed a general physical examination. Daily smoking log sheets (Appendix G) were issued to the participants in which each cigarette smoked was recorded. starting from after the initial consultation.

A copy of "Coping with Withdrawal" (Medical Association of South Africa, nd) (Appendix H) was also handed out at the initial consultation.

Patients were instructed to commence with the process of smoking cessation from the first consultation.

3.6 Treatment

Patients in the placebo group were given 25ml 20% alcohol and the treatment group received 25ml of the Anti-Tobacco complex remedy, also in 20% alcohol. The patients were instructed to take 10 drops on the tongue 1-2 hourly for the first week, and thereafter 3-4 times daily for a period of four weeks (van Wyk 1999). The patients also received written information on how to take their homoeopathic medication (Appendix I). An independent person (the homoeopathic dispenser on duty) dispensed all medication.

The first follow-up took place one week following the initial consultation, the subsequent follow-ups being at weekly intervals for four weeks. At each follow-up consultation the patient's withdrawal symptoms were noted. Questionnaires were completed at the first and last consultation. During appointments two and three, additional treatment material was dispensed if necessary.

3.7 Statistical Analysis

3.7.1 **Daily Smoking Log Sheets** (Appendix G):

Results were statistically evaluated by means of the Mann-Whitney U-test, which compares the cigarette consumption between the two groups. The Wilcoxon signed ranks test was used to calculate and tabulate any significant difference in cigarette consumption within each group from consultation one to five.

3.7.2 **Questionnaire on Health Hazards of Smoking** (Appendix C):

Part A: assessed the patients estimate of reduced life expectancy due to the health risks of smoking. The score was obtained by subtracting A1 from A2. A low score of less than 5 years indicated that the participant was underestimating the health hazards of smoking.

Part B: assessed the education of the patient as to the health risks of smoking, with a high score of more than one or two items that are marked being an indication of an underestimation of the health risks of smoking. The mean values of the results of the Mann-Whitney U-test were then calculated

and tabulated to asses if there was a significant difference in education between the two groups from consultation one to five. The Wilcoxon signed ranks test was used to calculate and tabulate any significant difference in education within each group from consultation one to five.

3.7.3 **Tolerance Dependence Questionnaire** (Appendix D):

This questionnaire assessed pharmacological tolerance and dependence on nicotine as well as assessing the patient's perception of their smoking addiction. The lowest possible score for this test is 0 and the highest score is 28. The Mann-Whitney U-test was used to calculate a significant difference between the experimental and placebo group, before and after treatment. The mean values of the results of the Wilcoxon signed ranks test were calculated and tabulated to show any significant difference within the experimental and placebo treatment groups from consultation one to five.

3.7.4 **Questionnaire on Types of Smokers** (Appendix E):

Three types of smokers are distinguished according to their main reason for smoking, i.e. The Habitual Addictive type, the Reduction of negative affect type and the Positive affect type smokers (pleasurable relaxation, stimulation, sensorimotor manipulation). This questionnaire was completed at consultations one and five. Each category has a possible maximum average score of 5 and a minimum average score of 1 for that particular reason. Mean values of the results of the Mann-Whitney U-test were calculated and tabulated to show any significant difference between the two groups before and after treatment, and the Wilcoxon signed ranks test was

used to show any significant difference in the types of smokers within the two groups before the treatment.

CHAPTER FOUR

RESULTS

4.1 The criteria governing the admissibility of the data

Only data from the daily smoking log sheets and questionnaires collected by the researcher during this trial was used. The participants completed all questionnaires in the presence of the researcher.

Only the data of participants who recorded their cigarettes smoked and who had taken their medication according to Natura Homoeopathic Laboratory directions (Van Wyk, 1999) was utilised.

4.2 Statistical analysis

The Mann-Whitney unpaired two-tailed test was used to compare the experimental and placebo group.

H_0: There is no difference between the two groups.

H_1: There is a significant difference between the two groups.

In each case α was set at 0.05 (specified level of significance) and H_0 was rejected if $p < \alpha/2$ since the test is two-tailed.

The Wilcoxon signed ranks test was used to test for differences within the two different groups.

H_0: There is no difference between the consultations.

H_1: There is a significant difference between the consultations.

Again in each case α was set at 0.05 (specified level of significance) and H_0 was rejected if $p < \alpha/2$ since the test is two-tailed.

Frequencies and percentages are presented for each variable of the study.

A zero score by either group in a particular category is shown as a blank on the graph.

4.3 Comparison with respect to cigarette consumption between the two groups

4.3.1 Table 4-1: Demographic variables at entry

	Experimental (n=14) Mean	Placebo (n=16) Mean
% Male	57.1%	78.6%
Age (years)	32	32
Dependence score (0-28)	13.28	14.44
No. of cigarettes a day	20.57	22.06
Years smoked	13	13.75

4.3.2 Table 4-2: **Comparison in cigarette consumption between experimental and placebo groups**

The P-values of the Mann-Whitney U-test were calculated and are tabulated below:

	Medians Experimental vs. placebo		Probability value (P)
Before treatment	20.57	22.06	0.301
After treatment	7.93	9.94	0.517

In each case P is greater than 0.025. The null hypothesis is thus accepted for both groups. It was thus concluded that there was no significant difference in smoking cessation between the two groups before and after treatment (see Figure 4-1).

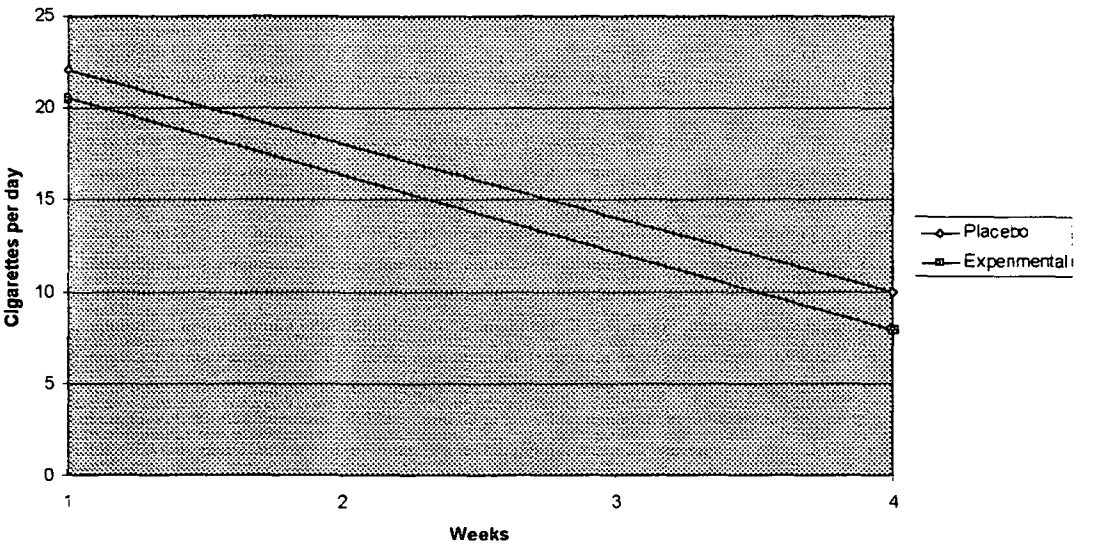
4.3.3 Table 4-3: **Comparison in cigarette consumption within the experimental and placebo groups before and after treatment**

The P-values of the Wilcoxon signed ranks test were calculated and are tabulated below:

	Means before vs. after treatment		Probability value (P)
Experimental	20.57	7.93	0.002
Placebo	22.06	9.94	0.001

The P-value for both the experimental and placebo group is less than 0.025; thus the null hypothesis was rejected. It was therefore concluded that there was a significant decrease (see means in Figure 4-1) in smoking cessation in both groups before and after the treatment.

4.3.4 Figure 4-1: **Median decrease in smoking over four weeks**



In comparing the differences between the total abstinence throughout the 5 week period between the experimental and placebo groups: 2 out of the 14 participants of the experimental group stopped smoking and 4 out of16 participants in the placebo group stopped smoking. The difference in cessation rates between the two groups was 12.64 (experimental) vs. 12.12 (placebo). On the whole the experimental group decreased smoking by 61.45% and the placebo group decreased smoking by 54.94%.

4.4 Questionnaire on the Health Hazards of Smoking - Part A

Part A: assessed the patients estimate of reduced life expectancy due to the health risks of smoking. The score was obtained by subtracting A1 from A2. A low score of less than 5 years indicated that the participant was underestimating the health hazards of smoking.

4.4.1 Table 4-4: Inter-group comparison with the Mann-Whitney U-test – Part A

The P-values of the Mann-Whitney U-test were calculated and are tabulated below:

Experimental vs. placebo	Median scores Experimental vs. placebo group		Probability value (P)
Before treatment	10	10	0.396
After treatment	7.5	7.5	0.495

Both groups had a score of more than 5 years before and after treatment, therefore neither group was underestimating the health hazards of smoking, although they had a decrease in their awareness towards the health risks by the fifth consultation.

In each case P is greater than 0.025. The null hypothesis is thus accepted for both groups. It was thus concluded that there was no significant difference in education between the two groups before and after treatment.

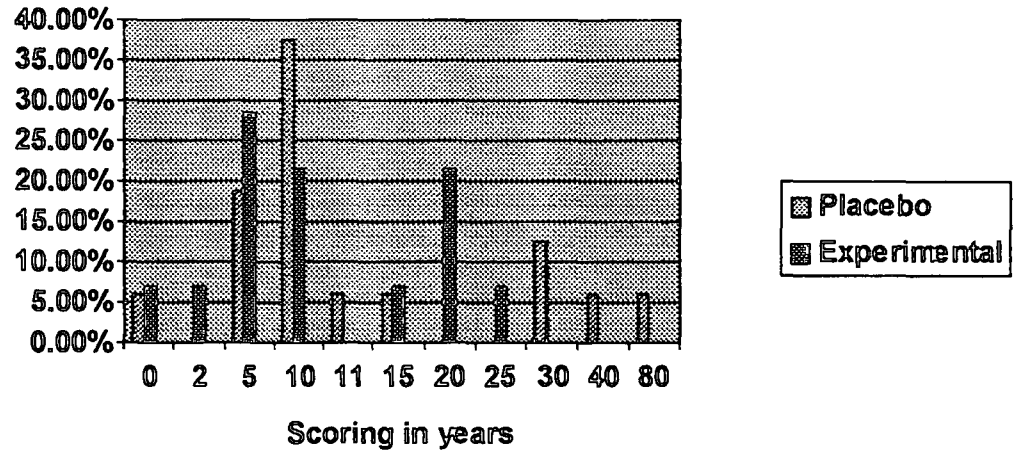
4.4.2 Table 4-5: Intra-group comparison with the Wilcoxon signed ranks test – Part A

The P-values of the Wilcoxon signed rank test were calculated and are tabulated below:

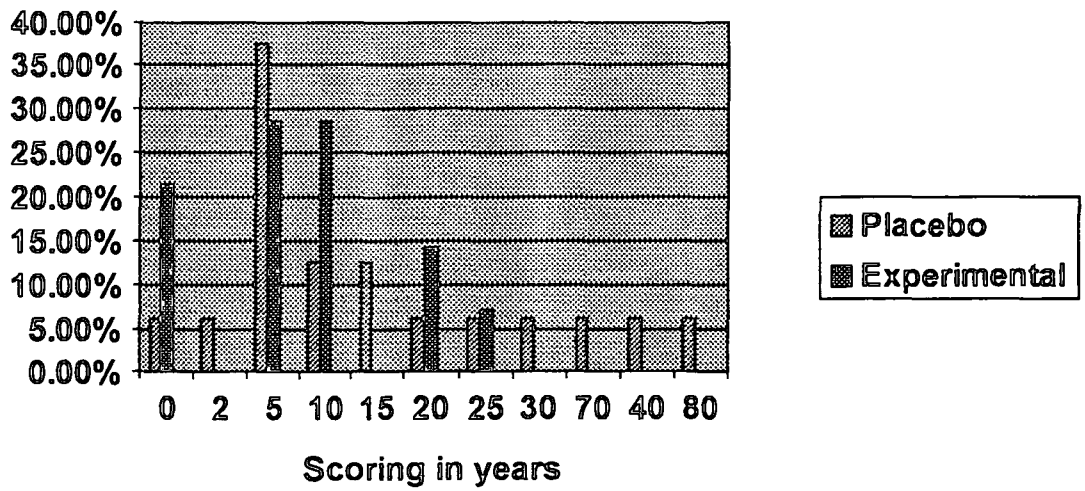
Before vs. after treatment	Median scores before vs. after treatment		Probability value (P)
Experimental	10	7.5	0.400
Placebo	10	7.5	0.048

The P-value for the placebo group is much closer to 0.025 than the experimental group; the placebo group is therefore tending towards significance although it is not significant at the 5% level. It was concluded that there was no significant difference in education within the experimental group from consultation one to five.

4.4.3 Figure 4-2: **Comparison in reduced life expectancy before treatment**



4.4.4 Figure 4-3: **Comparison in reduced life expectancy after treatment**



4.5 Questionnaire on the Health Hazards of Smoking - Part B

Part B: assessed the education of the patient as to the health risks of smoking, with a high score of more than one or two items that are marked being an indication of an underestimation of the health risks of smoking.

4.5.1 Table 4-6: Inter-group comparison with the Mann-Whitney U-test and mean percentages – Part B

The P-values of the Mann-Whitney U-test were calculated and are tabulated below:

	Mean percentages Experimental vs. placebo		Probability value (P)
Before treatment	23.94%	27.21%	0.542
After treatment	14.71%	27.58%	0.027

In each case the P-value is greater than 0.025 the null hypothesis is thus accepted. It could be argued that the P-value after the treatment which is 0.027 is practically equal to the level of significance which is $\alpha = 0.05/2$. Therefore one may consider the alternative hypothesis (there may be a significant difference in education between the experimental and placebo groups after the treatment).

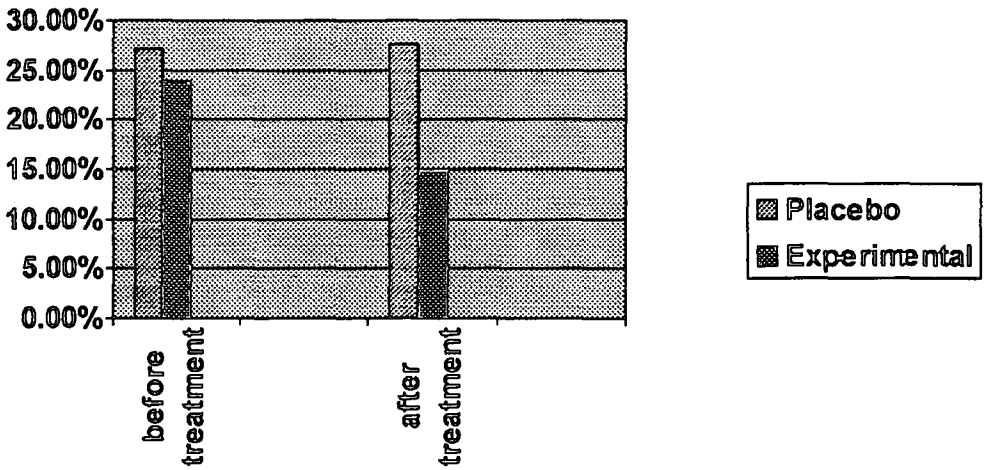
4.5.2 Table 4-7: **Intra-group comparison with the Wilcoxon signed ranks test and mean percentages – Part B**

The P-values of the Wilcoxon signed rank test were calculated and are tabulated below:

	Mean percentages before vs. after treatment		Probability value (P)
Experimental	23.94%	14.71%	0.067
Placebo	27.21%	27.58%	0.679

The P-value for the experimental and placebo group is greater than 0.025, thus the null hypothesis was accepted for both groups and it was concluded that there was no significant difference in education within each group from consultation 1 to 5.

4.5.3 Figure 4-4: **Comparison of the estimation of health risks of smoking before and after treatment**



There was a significant increase in the awareness of health risks of smoking the experimental group (see mean percentages Table 4-6 and Table 4-7) from consultation one to five. The placebo group however did not show any difference in their estimation of health risks of smoking after the treatment.

4.6 Tolerance Dependence Questionnaire

4.6.1 Table 4-8: Inter-group comparison with the Mann-Whitney U-test and mean percentages - Tolerance Dependence Questionnaire

The P-values of the Mann-Whitney U-test were calculated and are tabulated below:

	Mean percentages experimental vs. placebo		Probability value (P)
Before treatment	47.45%	51.56%	0.403
After treatment	38.27%	35.94%	0.950

In each case P is greater than 0.025 thus the null hypothesis is accepted and it can be concluded that there is no significant difference in tolerance dependence between the two groups from consultation one to five.

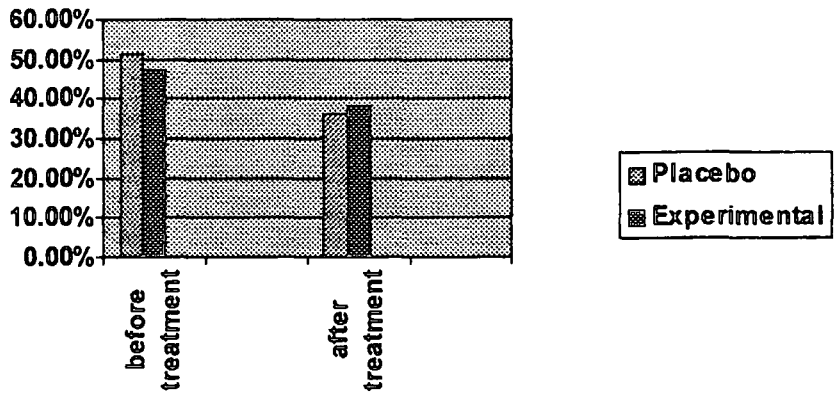
4.6.2 Table 4-9: **Intra-group comparison with the Wilcoxon signed ranks test and mean percentages - Tolerance Dependence Questionnaire**

The P-values of the Wilcoxon signed rank test were calculated and are tabulated below:

	Mean percentages before vs. after treatment		Probability value (P)
Experimental	47.45%	38.27%	0.113
Placebo	51.56%	35.94%	0.005

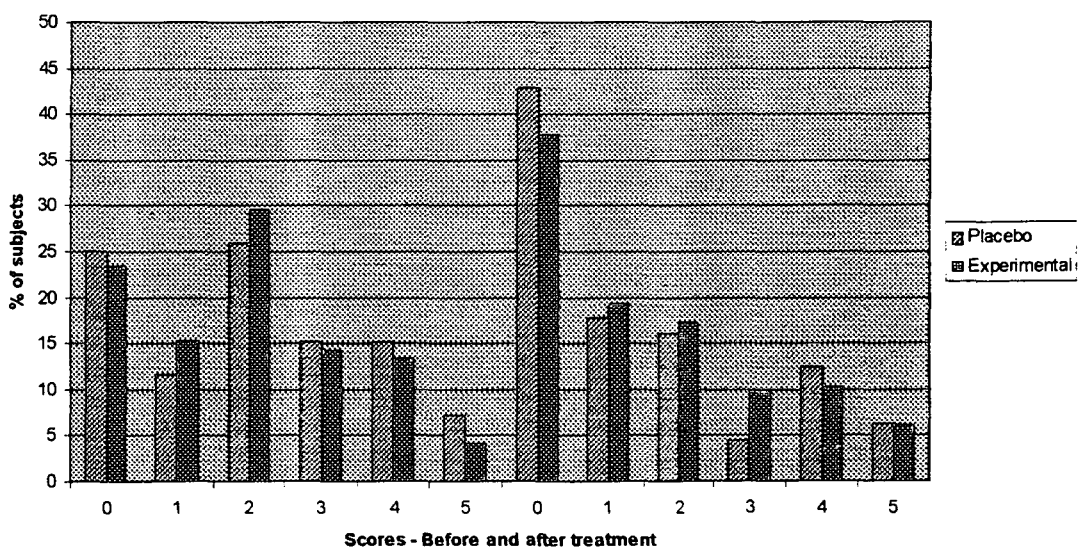
The placebo group showed a significant difference in tolerance dependence from consultation one to five (P=0.005). The experimental group showed no significant difference from consultation one to five since the P-value is greater than 0.025.

4.6.3 Figure 4-5: **Comparison between the two groups with reference to the Tolerance Dependence Questionnaire**



There was a significant decrease in cigarette dependence in both groups from consultation one to five (see Table 4-10 and Figure 4-6)

4.6.4 Figure 4-6: **Comparison of scores before and after treatment – Tolerance Dependence Questionnaire**



4.7 Questionnaire on Types of Smoking

4.7.1 Table 4-10: Inter-group comparison with the Mann-Whitney U-test – Questionnaire on Types of Smoking

The P-values of the Mann-Whitney U-test were calculated and are tabulated below:

	Experimental vs. placebo group	Mean percentages Experimental vs. placebo group		Probability value (P)
Habitual – addictive affect	Before treatment	56%	57.92%	0.631
	After treatment	48.2%	44.4%	1.000
Reduction of negative affect	Before treatment	77.59%	76.01%	0.722
	After treatment	70.61%	62.96%	0.441
positive affect	Before treatment	54.46%	52.96%	0.818
	After treatment	44.82%	47.50%	0.348

In each case P is greater than 0.025. The null hypothesis is thus accepted for both groups. It was concluded that there was no significant difference in the types of smoking between the two groups before and after the treatment.

4.7.2 Table 4-11: **Intra-group comparison with the Wilcoxon signed ranks test - Questionnaire on Types of Smoking**

The P-values of the Wilcoxon signed rank test were calculated and are tabulated below:

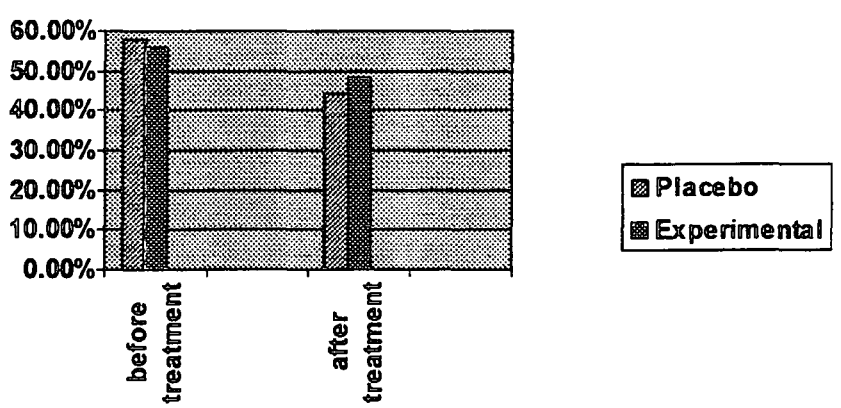
Before vs. after treatment	**Mean percentages before vs. after treatment**		**Probability value (P)**
Habitual addictive affect Experimental	56%	48.2%	0.008
Habitual addictive affect Placebo	57.92%	44.4%	0.003
Reduction of negative affect Experimental	77.59%	70.61%	0.148
Reduction of negative affect Placebo	76.01%	62.96%	0.016
Positive affect Experimental	54.46%	44.82%	0.021
Positive affect Placebo	52.96%	47.50%	0.095

The P-value was greater in the experimental reduction of negative affect and placebo positive affect smokers. The P-value of the rest was smaller than 0.025, the null hypothesis is therefore rejected and we can conclude that

there is a significant difference within those groups before and after treatment (see Figures 4-7 and 4-9).

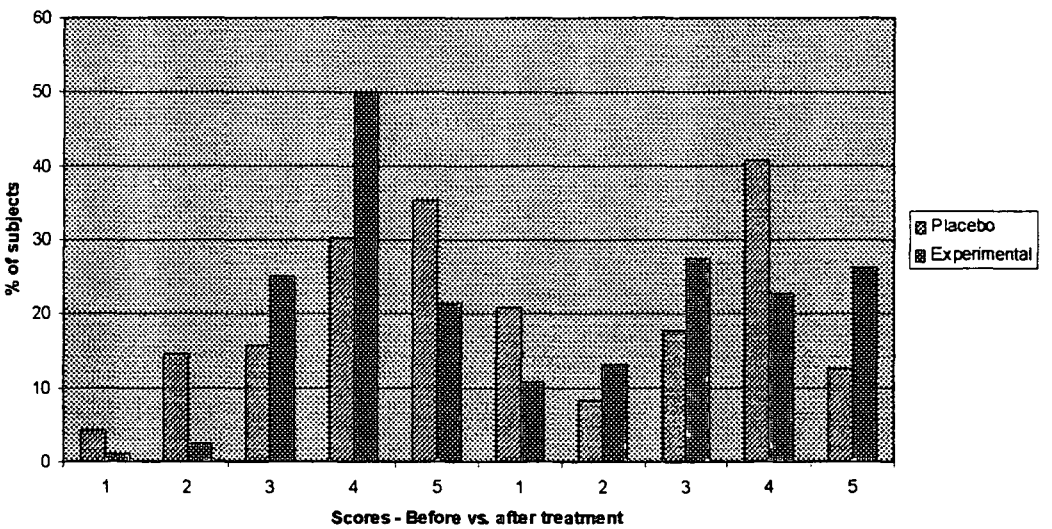
4.7.3 Figure 4-7: **Comparison of scores before and after treatment – Habitual addictive affect**

4.7.4 Figure 4-8: **Comparison of mean percentages before and after treatment - Habitual addictive affect**

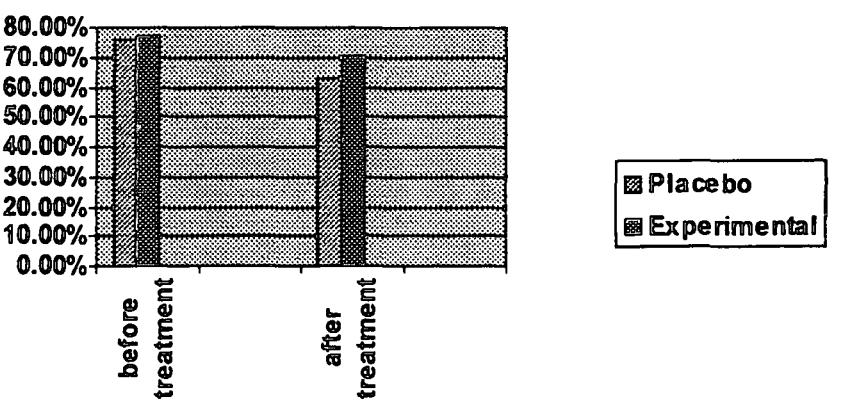


The scoring between the two groups indicated that the placebo group had a greater tendency to smoke due to habit than the experimental group before the treatment. After the treatment the experimental group smoked more due to habit than the placebo.

4.7.5 Figure 4-9: **Comparison of scores before and after treatment – Reduction of negative affect**

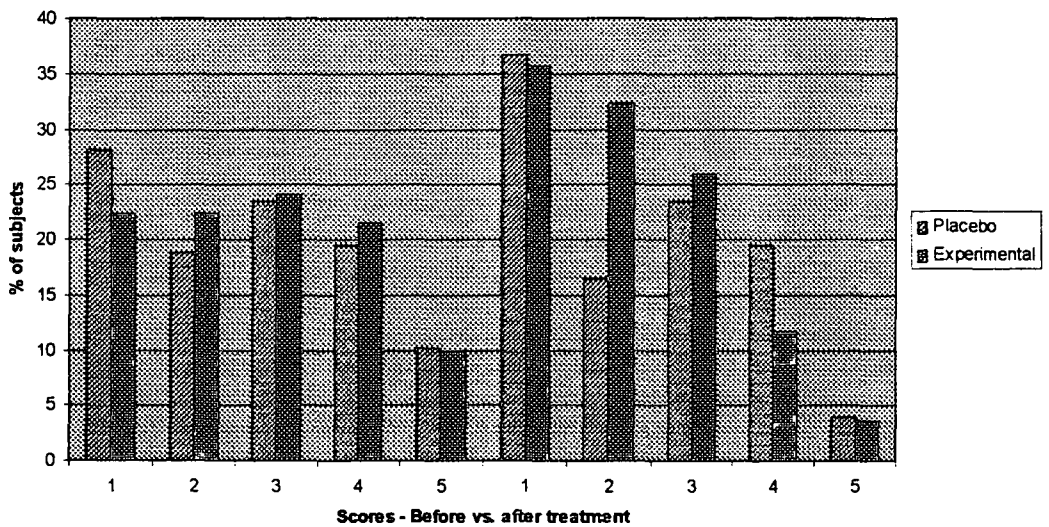


4.7.6 Figure 4-10: **Comparison of mean percentages before and after treatment - Reduction of negative affect**

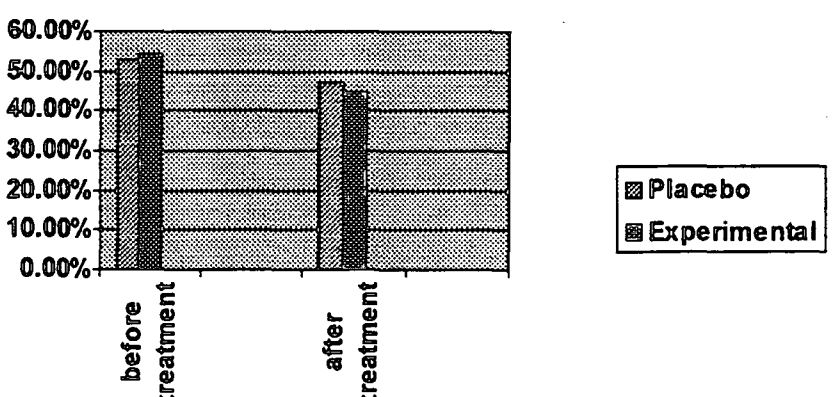


The scoring indicates than the experimental group smoked more for the reduction of negative affect before and after the treatment than the placebo group.

4.7.7 Figure 4-11: **Comparison of scores before and after treatment – Positive affect**



4.7.8 Figure 4-12: **Comparison of mean percentages before and after treatment - Positive affect**



The scoring indicates than the experimental group smoked more for positive affect before and after the treatment than the placebo group. Both groups had a decrease in tendency in smoking for positive affect after the treatment.

Summary for Types of Smoking

Both the experimental and the placebo groups had a greater tendency to smoke due to reduction of negative affect before and after treatment (see Table 4-10 and 4-11). Only one participant in the experimental group smoked due to habit before and after treatment.

CHAPTER FIVE

DISCUSSION

The results of this investigation indicate that both the Anti-Tobacco® complex and placebo have a statistically significant impact on reduction of cigarette consumption. The homoeopathic remedies in the Anti Tobacco® complex therefore do not necessarily reduce cigarette consumption.

In accordance with the theories of Breecher (1955), the placebo effect in homoeopathy is a contentious issue and again plays an important role in this study. One has to ask oneself the question of why did both groups show a significant decrease in smoking? The process of the study was important. Firstly, the participants who responded to the advertisement had to want to give up smoking. They then had to go through the effort of booking the appointment and then coming to report back on their progress, this study reinforces the importance of interpersonal direct management of smoking reduction as pointed out by Rigotti (2000) and Muers (1999). There was also an element in the participants to please the researcher. The participants were in other words monitored. This may have provided the most therapeutic input and might have provoked many of the participants to cut down and even give up their smoking habit. Therefore one must conclude that the reduction in smoking does not necessarily pertain to the product.

The original idea of this study was to evaluate the efficacy of Anti-Tobacco® on the different types of smokers. The first 40 volunteering participants were

included into the study and only one of those participants was classified as a habitual addictive type of smoker and the remaining 39 participants all smoked to reduce their negative affect. This however ties with the theory that people start and continue to smoke to "lift" their mood and to decrease their symptoms associated with depression (Jorm, et al. 1999). This again reinforces the need for support for smokers; it is of great importance since they are less likely to be able to stop smoking on their own (Lang, et al. 2000).

Another general observation was that the participants in the study that were in the older age group of more than about 35 years seemed more interested in actually giving up their smoking addiction, whereas the people in the younger age group did not seem to care as much. They would also give in to the cigarette craving a lot faster (see recommendation number 3).

One patient also reported that he had stopped smoking cannabis (see recommendation number 9).

CHAPTER SIX

CONCLUSIONS AND RECOMMENDATIONS

On the basis of the results of this study it seems that Anti-Tobacco® does not have a role to play in the management of cigarette addiction, but any process of direct management of smoking addiction is likely to prove effective.

Recommendations for further studies:

1. One should use a larger sample size to give an equal distribution of types of smokers to be included in this study.

2. One of the inclusion criteria should specify that equal number of participants should fall in equal numbers into the three different classifications of smokers.

3. It would be interesting to compare two different age groups of smokers in respect to the efficacy of the Anti-Tobacco® complex.

4. Natura Homoeopathic Laboratory manufactures the OTC Anti-tobacco complex used in this study and it is preserved in 20% alcohol. There is a definite correlation that is known to exist between alcohol and smoking (Burton and Tiffinay, 1997). A recommendation to Natura Homoeopathic Laboratory would be to manufacture the product in tablet form.

5. A further research option would be to evaluate the efficacy of the Anti-Tobacco® complex in tablet or granule form in the efficacy of the management of cigarette addiction.

6. An evaluation of the efficacy in comparing a homoeopathic similimum treatment with a homoeopathic complex in helping people to stop smoking.

7. It would also be beneficial in further studies to monitor the smoking status of the patient by measuring the correlation coefficient between the number of cigarettes smoked per day as stated by the patient and the expired carbon monoxide level (Lang et al. 2000).

8. A new homoeopathic Anti-Tobacco complex could be formulated that include more remedies that treat the depressive symptoms that may arise in some patients during smoking cessation.

9. Another study may be conducted on the efficacy of the Anti-Tobacco® complex in helping people with cannabis dependence.

10. According to Davidson (1996), if the results show no significant difference between placebo and experimental groups in a placebo-controlled study, one must repeat the study. If the homoeopathic response pattern persists on repetition and those of the placebo are inconsistent, it is probable that one is dealing with a treatment that is

effective. Therefore, one should try and minimise the placebo effect. A recommendation arising from Davidson's (1996) perspective would be to repeat this study, but omit regular contact between the researcher and participants, by only measuring cigarette consumption before and after the study.

11. It is also recommended that before patients commence the treatment they must keep a seven-day diary of cigarettes smoked, in order for the researcher to get an accurate figure at the beginning of the study.

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LIST OF 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):_____

Cellular Phone:_____

MEDICAL HISTORY:

Operations:_____

_____

_____

Serious Illnesses:_____

_____

Current Medication:_____

_____

(Please note that current medication includes other homoeopathic medicines, vitamins and the contraceptive pill.)

_____

Appendix B

INFORMED CONSENT FORM

(To be completed in duplicate by patient)

TITLE OF RESEARCH PROJECT:

An evaluation of the efficacy of a homoeopathic complex remedy in the management of cigarette addiction.

NAME OF SUPERVISOR: Dr G. McDavid

NAME OF CO-SUPERVISOR: Dr R. Steele

DATE OF FIRST APPOINTMENT:_____

PLEASE CIRCLE THE APPROPRIATE ANSWER

1. Have you read the research information sheet? YES/NO
2. Have you had an opportunity to ask questions regarding this study? YES/NO
3. Have you received satisfactory answers to your questions? YES/NO
4. Have you had an 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 reason 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 this study? YES/NO
11. Do you understand the difference between a placebo and homoeopathic treatment? YES/NO

PATIENT/SUBJECT* Name: _____ SIGNATURE _____
(in block letters)

WITNESS Name: _____ SIGNATURE _____
(in block letters)

RESEARCH STUDENT Name: Nicolette Hellberg SIGNATURE _____

Appendix C

QUESTIONNAIRE ON HEALTH HAZARDS OF SMOKING

(Goldstein 1988:2-1 - 2-3)

PART A

1. If you quit smoking right away, at what age (barring unforeseen accidents) might you honestly predict you would die?

A1 _____

2. If you continued to smoke (and barring unforeseen accidents), at what age might you honestly predict you would die?

A2_____

PART B

DIRECTIONS: Below are some statements, which are frequently given as reasons why a person continues to smoke. Please tick the ones that you could endorse or go along with.

1. The relationship between smoking and cancer has not really been proven. _____

2. Smoking probably won't shorten my life by more than five years, and it's better to enjoy life now than to live five years longer and be unhappy. _____

3. I am truly addicted and therefore unable to stop. _____

3. We do not stop the use of alcohol or automobiles, yet they are more dangerous than cigarettes. _____

5. I have to smoke to relieve my nerves. _____

6. I smoke filter tips; the harmful material has largely been removed. _____

7. When I stop smoking I gain weight and that is just as bad. _____

8. Anything (including cigarettes) is good in moderation and bad in excess. _____

9. I personally know of at least one very old person who has smoked most for his life yet who continues to be in fine health. _____

10. Cancer comes with age and heredity. There is no cancer in my family so therefore I need not worry much about it. _____

11. Hydrogen bombs, highway accidents, murders, alcoholism, suicide there is no safety anywhere, so why worry? _____

12. The pleasure I get, which is certain, outweighs the health hazard, which is uncertain. _____

13. The emotional effects of my going without cigarettes are more hazardous to me than is smoking. _____

14. Scientific research will develop a "safe" cigarette before too long, and the effects of my smoking between now and then are probably insignificant. _____

15. Under present conditions, who wants to live long? _____

16. God would not have put the tobacco plant on earth if He did not have some non-harmful purpose in mind. _____

17. So smoking proves I am weak willed? Everybody is entitled to ones weakness. _____

TOLERANCE DEPENDENCE QUESTIONNAIRE

(Adapted from Goldstein 1988:11-7)

DIRECTIONS: Underline the answer that you find most appropriate for each question.

1. How soon after you wake up do you smoke your first cigarette?

(3) Within 5 minutes
(2) 6 - 30 minutes
(1) 31- 60 minutes
(0) 61- or more

2. Do you find it difficult to refrain from smoking in places where it is forbidden (for example in church. cinema, library etc.)?

(4) Always
(3) Frequently
(2) Occasionally
(1) Seldom
(0) Never

3. Which cigarette of the day would you most hate to give up?

(5) The cigarette of the morning
(4) Midmorning
(3) Midday
(2) Midafternoon
(1) Night
(0) Any other

4. How many cigarettes do you smoke per day? _____

(4) 37 or more
(3) 27 - 36
(2) 17 - 26
(1) 7 - 16
(0) 6 or less

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

(4) Always
(3) Frequently
(2) Occasionally
(1) Seldom
(0) Never

6. Do you smoke so much that you spend the day ill in bed?

(4) Always
(3) Frequently
(2) Occasionally
(1) Seldom
(0) Never

7. Do you usually inhale?

(4) Always
(3) Frequently
(2) Occasionally
(1) Seldom
(0) Never

Appendix E

QUESTIONNAIRE ON TYPES OF SMOKING

(Goldstein 1988:11-9 - 11-10)

DIRECTIONS: Write down the number allocated to the answer that you find most appropriate to the question. The scoring is as follows:

SCORE:	ALWAYS 5	FREQUENTLY 4	OCCASIONALLY 3	SELDOM 2	NEVER 1

1. I smoke cigarettes to stimulate me, to perk myself up. _____
2. I have found a cigarette in my mouth and did not remember putting it there. _____
3. When I am trying to solve a problem, I light up a cigarette. _____
4. When I smoke a cigarette, part of the enjoyment is watching the smoke as I exhale it. _____
5. I am very much aware of the fact when I am not smoking a cigarette. _____
6. Part of the enjoyment of smoking a cigarette comes from the steps I take to light it up. _____
7. When I feel "blue" or want to take my mind off cares and worries, I smoke cigarettes. _____
8. I smoke cigarettes automatically without even being aware of it. _____
9. I smoke cigarettes in order to keep myself from slowing down. _____
10. I get a real gnawing hunger for a cigarette when I have not smoked for a while. _____
11. When I feel uncomfortable or upset about something, I light up a cigarette. _____
12. Handling a cigarette is part of the enjoyment of smoking it. _____
13. Between cigarettes, I get a craving that only a cigarette can satisfy. _____
14. I light up a cigarette when I feel angry about something. _____

15. I light up a cigarette without realising I still have one burning in the ashtray. _____

16. I find cigarettes pleasurable. _____

17. When I have run out of cigarettes I find it almost unbearable until I can get them. _____

18. When I feel ashamed or embarrassed about something, I light up a cigarette. _____

19. Few things help better than cigarettes when I am feeling upset. _____

20. I smoke cigarettes just from habit, without even really wanting the one I am smoking. _____

21. Smoking cigarettes is pleasant and relaxing. _____

22. I do not feel contented for long unless I am smoking a cigarette. _____

23. I smoke cigarettes to give me a "lift". _____

Appendix F

METHODS OF SCORING FOR THE QUESTIONNAIRE ON TYPES OF SMOKING

(Goldstein 1988:11-10)

Add scores for items and divide as indicated for AVERAGE SCORE:

	HABITUAL-ADDICTIVE	REDUCTION OF NEGATIVE AFFECT	POSITIVE AFFECT
	2. _____ 5. _____ 8. _____ 10._____ 13._____ 15._____ 18._____ 20._____ 22._____	3. _____ 7. _____ 11._____ 14._____ 17._____ 19._____	1. _____ 4. _____ 6. _____ 9. _____ 12._____ 16._____ 21._____ 23._____
TOTAL	Divide by 9	Divide by 6	Divide by 8
AVERAGE SCORE	=	=	=

Appendix G

DAILY SMOKING LOG SHEET

Date:_____ Appointment number:_____

Cigarette number	Trigger (preceding event or emotion)	Cigarette number	Trigger (preceding event or emotion)
1		16	
2		17	
3		18	
4		19	
5		20	
6		21	
7		22	
8		23	
9		24	
10		25	
11		26	
12		27	
13		28	
14		29	
15		30	

Appendix H

COPING WITH WITHDRAWAL

(The Medical Association of South Africa)

You may notice a few physical and mood changes after you stop. These will last a few days after quitting and are perfectly normal.

SYMPTOM	REASON FOR SYMPTOM	COPING ACTIVITY
Craving	Your body is used to getting Regular "fixes" of nicotine	The strong urge to smoke usually lasts 2-5 minutes before fading away. Do something to occupy yourself until the feeling passes - drink water , breathe deeply etc
Light headedness and loss of concentration	Light headedness and loss of concentration	Take things more slowly. Do not push yourself too hard for the next few days. Get regular exercise. Work for short periods and then take a break. Make sure you eat properly.
Coughing	Your lungs are clearing out the tars and excess mucus	Sip warm water. The coughing will soon clear up by itself.
Tension, irritability	Low blood nicotine levels	Take a walk, soak in a hot bath, and try relaxation techniques. Talk to someone about your feelings.
Depression	Feeling helpless, incompetent and worthless due to emotional confusion	Modest exercises (a five or ten minute brisk walk) can help lift your mood. Try dealing with your problems one by one or bit by bit
Hunger	Your body's metabolism is returning to normal	Eat popcorn, carrots, prunes and other low calorie snacks. Try to eat 6 small meals a day. Drink lots of water.
Trouble sleeping		Soak in the bath and have a glass of hot milk before going to bed. If you cannot sleep, get up and read - or listen to the radio. Exercising before going to bed can also help.

Other common symptoms: dry mouth, sore throat, headaches, digestive problems, fatigue, bouts of tearfulness and mouth ulcers.

Appendix I

HOW TO TAKE YOUR HOMOEOPATHIC REMEDIES

1. Take 10 drops preferably on the tongue or in a little water 1-2 hourly for the First week. Thereafter 3-4 times daily or when necessary.

2. Take your remedies **away from meals** at least 1/2 hour before a meal or one hour after.
Avoid eating **MINT** before or after taking medication.

3. The remedies must be stored away from **camphor** (e.g. Vicks products) light, heat and electromagnetic radiation (T.V's, computers, etc)

4. Try to avoid the intake of coffee during your treatment.

FOR ANY QUERIES REGARDING YOUR MEDICATION, PLEASE DON'T HESITATE TO CALL THE TECHNIKON NATAL HOMOEOPATHIC DAY CLINIC ON TEL NO. 2042041.

INFORMATION SHEET

Tobacco smoking is one the chief avoidable causes of premature death and ill health in the world.

This study will propose to determine the impact of homoeopathic treatment on this condition and how effective it is in helping people to stop smoking.

In order to do this, we appeal to you for assistance by becoming actively involved and informing us about your daily smoking habits and any additional symptoms that go with them.

Subjects will be divided into two groups: namely the treatment group and the placebo group. If you were in the placebo group on completion of the study, you will receive free treatment to help you stop smoking, if you wish. A placebo is made of a medicinally inactive substance used in controlled studies for comparison with presumed active drugs.

The following questionnaires will give you the opportunity to do just that and your honest and objective contribution will enable us to determine the effect of homoeopathy on tobacco addiction and the role homoeopathy can play in this area of public health.

Thank you for your co-operation in this research project.

Nicolette Hellberg.