

THE RELATIVE EFFECTIVENESS OF ISOTHERAPY
COMPARED TO ISOTHERAPY AND SIMILLIMUM IN
MANAGING TOBACCO SMOKING ADDICTION

by

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Technology: Homoeopathy, in the Faculty of Health at the Technikon Natal.

I, Joanne Pautz, do declare that this dissertation is representative of my own work.

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This dissertation is dedicated to my wonderful parents for their love, support and guidance, who kept me inspired throughout my studies.

Thank-you.

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ABSTRACT

The purpose of this study was to investigate the use of isotherapy together with the homoeopathic simillimum whilst comparing it with isotherapy combined with placebo in helping people to stop smoking, in terms of a daily smoking log, and the participants attitude to their tobacco smoking addiction.

Thirty participants completed this double-blind randomised trial which took place in the northern suburbs of Gauteng. Participants responded to advertisements and were selected according to certain criteria: participants were to be over the age of 18 years of age, and were to have smoked 15 or more cigarettes a day for more than a year.

Group 1 received isotherapy and homoeopathic simillimum and group 2 isotherapy and placebo. Each participant received 5 treatments over a period of 3 months. Cigarette consumption was recorded daily by each participant and questionnaires were completed in the presence of the researcher at each consultation. The daily smoking logs and the questionnaire scores were totalled and statistically analysed. Comparison with respect to cigarette consumption between the two groups were analysed using the two-sample unpaired t-test. The Mann-Whitney U-tests were used for inter-group comparisons and the Wilcoxon's signed rank tests for intra-group comparisons with respect to the questionnaires. Data was presented in tables and bar graphs. In each case α was set at 0.05.

There was a significant difference between the experimental and placebo groups after treatment with regard to cigarette consumption and nicotine tolerance/ dependence. Efficacy was highly significant for the experimental group with respect to the mean daily consumption of cigarettes. Mean daily consumption decreased by 80.22% in the experimental group and by 51.11% in the placebo group. Total abstinence rates among the experimental group was 11.8% compared to 7.7% of the placebo group.

The results of this study demonstrated that homoeopathic simillimum together with isotherapy is an aid in helping people to stop smoking.

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DEFINITION of TERMS

ISOTHERAPY is the treatment of disease by a pathogenic agent from the environment: allergen, ill-tolerated or toxic substances (Jouanny et al. 1994: 65).

PLACEBO is any therapy or component of therapy that is deliberately used for its non-specific, psychological, or psycho-physiological effect, or that is used for its presumed specific effect, but is without specific activity for the condition being treated (Shapiro and Morris 1978: 369).

SIMILLIMUM is the Homoeopathic remedy, chosen from the entire range of Homoeopathic remedies, whose pathogenetic action matches the symptom picture of the patient (Jouanny 1991: 92).

CHAPTER ONE

INTRODUCTION

For many people smoking is actually one of the important pleasures in life. The problem is that smoking is also a killer. Cigarettes have been called “coffin nails” or “cancer sticks” over the years - and for good reason. (Goldstein 1988: 1.)

At the ninth World Conference on Tobacco and Health held in Paris (October, 1994) the health impact on current and future tobacco use was discussed. A global increase of tobacco-related deaths is expected to increase from 3 million annually in 1990 to 10 million in the 2020's. Of these deaths in the 2020's, 70% will occur in developing countries. (Peto 1994.) McGinnis *et al.* (1992) found that at least 75% of adult smokers are hooked before the age of 21 and 90% have tried, most of them unsuccessfully, to quit.

Di Nepi (1990) states that isotherapy is complementary to homoeopathic treatment, allowing for a deeper action, especially in chronic conditions. Research conducted at Technikon Natal comparing isotherapy and acupuncture in giving up smoking suggests future trials using homoeopathic remedies commonly used for addictions in conjunction with isotherapy, and to compare this with placebo in double blind trials

(de la Rouviere 1996). No other studies could be traced in which isotherapy was used in the cessation of smoking.

As homoeopathy is individualistic, it will be expected that the reasons for smoking as well as the withdrawal syndrome will vary greatly among the participants in this study. The difficulties encountered before and after nicotine withdrawal will hopefully be counteracted with a homoeopathic simillimum which, if chosen correctly, will act on the physical, emotional and mental spheres of the addiction.

CHAPTER TWO

REVIEW OF THE RELATED LITERATURE

2.1 SMOKING AND DISEASE

Coupled with lung cancer, coronary heart disease accounts for the most common tobacco-related fatal conditions. Between the ages of 30 - 49 years non-fatal myocardial infarction rates are five times as great among smokers as among non-smokers, three times as great at ages 50 - 59, and twice as great at ages 60 - 79. In comparing tar yields as they would relate to non-fatal myocardial infarction rates, it was found that the risk was 10.4% higher in medium tar than in low tar cigarette smokers. (Parish et al. 1995.) Mackay (1991) points out that lung cancer is rarely curable and that the key to reducing its frequency lies in prevention. He says that tobacco smoking is responsible for 90% of lung cancer.

Smoking impairs both thyroid hormone secretion and thyroid hormone action. Smoking status should be considered in patients in whom hypothyroidism is suspected. (Muller et al. 1995.) Nicotine does seem to be effective in reducing the acute manifestations of ulcerative colitis but it has been found to be ineffective as a

maintenance therapy for the disease. The underlying abnormality responsible for the relapsing nature of the condition persists when treated with transdermal nicotine.

(Gareth et al. 1995.) Non-insulin dependent diabetes mellitus risks were almost doubled in men who smoke cigarettes than in abstainers. Smoking has been shown to have unfavorable long-term effects on insulin secretion and insulin resistance. (Rimm et al. 1995.)

Published studies of smoking and breast cancer showed that there was a modest increase in the risk of developing cancer among women who had smoked for more than 30 years. The smokers with breast cancer were 8 years younger than non-smokers with breast cancer. This does not support the hypothesis that the anti-oestrogenic effects of the cigarette protects the women against breast cancer, this being the commonest cancer in women throughout the world. (Bennicke et al. 1995.)

Rosevear et al. in 1992 proved that infertility is effected by cigarette smoking by virtue of the fact that it is associated with reduced fertilisation of eggs to about two-thirds of the normal rate. It is therefore advisable for a couple wishing to conceive to both stop or at least to reduce smoking habits. According to the Merck Manual (1992), infants born to mothers who smoke have a mean birth weight of 6 oz. less than that of infants born to non-smoking mothers. Pregnant smokers have a higher incidence of abruptio placentae, placenta previa, premature rupture of the membranes and amniotitis. Anencephaly, congenital heart defects, and orofacial clefts are reported more frequently in infants of smokers than in those of control subjects.

Statistical studies have shown that smokers are several times more prone to have peptic ulcers as are nonsmokers (Guyton 1987). Many other diseases are associated with smoking - arteriosclerosis, cataracts, chronic bronchitis, colo-rectal cancer, diarrhoea, emphysema, heartburn, high blood pressure, impotence, respiratory ailments, urinary incontinence, circulatory ailments, and cancers of the mouth and throat (J. Balch and P. Balch 1997).

2.2 SMOKING AND DIETS

Margetts and Jackson (1996) carried out a survey among British adults who smoke, according to their diets and nutritional requirements. Their diets were found to be deficient in nutrients - their food choices included more white bread, sugar, meat and butter than the diets of non-smokers. The smokers' diets were low in anti-oxidants and the cigarette itself produced free radicals. Smoking also creates a need for specific, unusual nutrient requirements such as B-carotene. The smokers were thus found to be more susceptible to oxidative, degenerative diseases. Smoking can reduce vitamin C levels by as much as 30%, vitamin E, however seems to neutralize the free radicals in cigarette smoke (Williams 1989).

Smoking cessation has been suggested as a factor contributing to the increased prevalence of obesity. Among United States adults there was no significant differences in weight gain between those who had never smoked and those who has quit smoking

more than 10 years previously. This suggests that weight gain occurs shortly after smoking cessation and that former smokers do not continue to gain weight at a higher rate than those who have never smoked. These former smokers however were still more likely to be overweight than those who continued to smoke. Despite its long-term health benefits weight gain over a 10 year period was 4.4 kgs for men and 5 kgs for women. For men about a quarter of the increase could be attributed to smoking cessation within the last 10 years, for women about a sixth. (Richard et al. 1995.) According to Carr (1995), “the weight myth is due to using substitutes during the withdrawal period”.

Caffeine was shown by Hepple and Robson (1996) as an aid to giving up smoking in ex-smokers. Nicotine itself causes increases in the pulse rate, blood pressure and in the general arousal state in the body. In the decaffeinated participants of the trial these appetitive states increased on exposure to smoking cues. Caffeine reduced or protected the ex-smoker against the intensity of these surges.

2.3 SMOKING AND ALCOHOL

Alcohol consumption has a direct impact on cigarette craving. This is a pharmacological rather than an expectancy influence as the effect was obtained relative to control subjects who believed they had consumed alcohol. A clinical implicative of this study is that smokers attempting to quit may find the combination of smoking cues and alcohol presents a strong threat to their continued abstinence. (Burton and Tiffany 1997.)

2.4 SMOKING AND PSYCHOLOGY

Carr (1995) says that one of the reasons that cigarettes and most drugs are difficult to abstain from is because it is when you are not smoking that you suffer an empty, anxious feeling - you do not blame the cigarette but are fooled into believing that the drug is some sort of pleasure. He maintains that smokers do not smoke because they enjoy it, they do it because they are miserable without it. Burton and Tiffany (1997) found that subjects on cigarette trials reported more negative mood and less positive mood than those on neutral trials. The incidence of smoking initiation was higher among people with depressed mood, a history of major depression, or both conditions than among people who were not depressed (Escobedo et al. 1996).

2.5 SMOKING CONSTITUENTS

Over 4,000 chemical substances have been identified as constituents of cigarette smoke, and at least 43 of these substances are known to cause cancer in humans.

Cigarette smoke contains carbon monoxide, benzene, cyanide, ammonia, nitrosamines, vinyl chloride, radioactive particles, and other known irritants and carcinogens.

(J.Balch and P.Balch 1997.) The nicotine content of just one cigarette, if injected directly into a vein, would kill you. It takes three weeks for 99 per cent of the nicotine to leave your body. (Carr 1995.)

2.6 SMOKING CESSATION DEVICES

Several studies have been conducted as to the therapeutic effectiveness of nicotine replacement therapy in helping people to stop smoking. These products allow weaning from nicotine while maintaining partial reinforcement of the ritual / sensory phenomena of smoking. These studies reveal long-term success rates ranging between 7% to 19%. (Russell et al. 1993; Silagy 1994; Sutherland et al. 1992; Tang et al. 1994; Henningfield 1995; Mendelsohn and Richmond 1995.) Side effects of nicotine patches include itching, local erythema and insomnia (Mendelsohn and Richmond 1995). Side effects of nicotine chewing-gum include burning and ulceration of the mouth, throat irritation, dyspepsia, nausea, hiccups, and temporomandibular arthralgia.

It also causes discomfort by sticking to dentures. (Tang et al. 1994.) Participants using a nasal nicotine spray in a trial for smoking cessation found the spray caused a sore area in the nostril, blocked nose, nasal blood spotting, nasal ulceration and vomiting (Sutherland et al. 1992). The nicotine inhaler included side-effects such as throat/mouth irritation and coughing (Schneider et al. 1996). Nicotine replacement therapy is contraindicated in people with diseases of the heart and blood vessels or in pregnant or nursing women. Continuing to smoke while using these products may increase the risk of nicotine toxicity and adverse cardiac events. (Tang et al. 1994.)

In nicotine medications the strategies needed for optimal use, according to Henningfield (1995) vary from patient to patient, some require higher doses, longer-term use, combinations of dosage forms, and possibly new dosage forms. In comparing the different forms of nicotine replacement therapies the most effective was the nicotine inhaler, followed by the nasal spray, the transdermal patch and then the nicotine gum (Silagy et al. 1994).

2.7 SMOKING INTERVENTION

Mackay (1991) explains how the tobacco industry is our biggest obstacle to success in controlling tobacco-related diseases, especially in developing countries where there are fewer legislative controls. He says it is important that all countries should support anti-tobacco activities. A total ban on all tobacco promotion, advertising and sponsorship should be made. New forms of tobacco products should be banned so that an "additional range of cancers" cannot be launched. Mackay also suggests that doctors should be more involved with prevention, rather than cure, they should set an example by not smoking and they should find lively ways of presenting statistics accurately. Litigation is a relatively new development in the "tobacco war" and could mean serious financial implications for the tobacco industry, hopefully bringing them to their knees. Findings in February 1994 by an American television investigative news program concluded that tobacco companies manipulate the nicotine content of tobacco products to facilitate nicotine addiction (Henningfield 1995). Carr (1995) says that it is ironic that mankind spend thousands of pounds on cancer research, yet millions are spent persuading young, healthy people to become addicted to cigarette smoking, the government having the largest vested interest.

Midwives were assessed as to the amount of smoking intervention they currently practiced. Most of them used minimal intervention (advice and education) for at least some of their clients. Half their smoking clients were not offered any advice about smoking. Fifty percent of the midwives received no training in the management of

substance use disorder, fifty percent had less than 4 hours training. Most of them felt their barriers in using smoking intervention were a lack of self confidence and insufficient time. (Cooke et al. 1996.)

Workplace smoking bans were developed in the hope that 24 hour smoking frequency would fall. Results from an observational study in the workplace showed that smoking bans in the workplace caused smokers to smoke 9% "harder" than cigarettes smoked in a social setting. The well-intentioned compassion by employers to give smoke breaks may be misguided as this increased puffing frequency per cigarette does not, in effect allow the 24-hour smoking frequency to fall in their workers. It has been suggested that employees clock off if they leave the building to smoke as employees with other forms of dependency (e.g. alcohol, narcotics, gambling) do not have workplace policies that permit them to leave their work briefly, in order to satisfy their desires. (Chapman et al. 1997.)

The best people to target would be those of a low socioeconomic status as those who are less educated have higher rates of smoking than do other people. Data also shows a direct association between smoking initiation and depression. Life skills education among adolescents need to be addressed. (Escobedo et al. 1996.) Jarvis (1996) found that adults with dependent children were more likely to have given up smoking than those without, he suggests attempting to persuade adults to consider their role as parents when thinking about giving up smoking may be a fruitful health education approach.

2.8 HOMOEOPATHY

The homoeopathic consultation is therapeutic in itself provided the therapist has a caring, positive, warm attitude and does not necessarily condone his patients behavior (Ledermann 1985).

In the study on midwives they suggest that practitioners should personalize each consultation, provide advice to quit, offer some self-help material, negotiate a plan for quitting if appropriate and identify social support. It is advised that follow-up sessions provide reinforcement and relapse prevention. (Cooke *et al.* 1996.) Compared with people who did not suffer from depression, the likelihood of initiating the smoking habit was greater amongst those who were diagnosed with depression. An emphasis on counselling in subjects such as improving decision making, increasing assertiveness, improving self-esteem and offering alternatives to smoking when confronted with problems, may reduce the likelihood of smoking among adolescents who are depressed. (Escobedo *et al.* 1996.) Homoeopathy increases the addicts ability to succeed in breaking his habit and helps him to come to terms with the underlying cause (Lee 1992).

Homoeopathic treatment helps in reducing the withdrawal symptoms (Lee 1992).

These symptoms include irritability, frustration, anger, anxiety, difficulty concentrating, restlessness, increased appetite, headache, stomach cramps, a slowed heart rate and a rise in blood pressure (J.Balch and P.Balch 1997).

According to De Nepi (1990) isotherapy should not be used alone but should complement homoeopathic or conventional treatment. He says that one can reduce the dosage of conventional medication whilst using isotherapy. Jouanny et al. (1994) describes isotherapy as pharmacological preparations of allopathic drugs that were taken by the patient and advises using isotherapy indirectly when the pathogenic agents are from the environment such as allergens, ill-tolerated or toxic substances.

CHAPTER THREE

MATERIALS AND METHODS

3.1 STUDY DESIGN

The following steps were taken in the execution of study:

- ~ Advertisements for participation in a clinical trial involving homoeopathic treatment in giving up smoking were placed on notice boards of public places and in local newspapers.
- ~ An assessment was carried out as to whether the people who responded to the advertisement were suitable for the study.
- ~ The researcher explained the program to the patient and answered any questions.
- ~ If he/she were accepted into the study, they completed the following documentation on the first visit: Patient Consent Form (Appendix A), Questionnaire on Health Hazards of Smoking, Tolerance Dependence Questionnaire, Questionnaire on Types of Smoking (Goldstein 1994) (Appendix B).
- ~ Each patient completed the questionnaire in the presence of the researcher.
- ~ Daily smoking logs were issued to the participants in which each cigarette smoked was to be recorded, starting from the initial consultation (Appendix C).

- ~ A copy of "Coping with Withdrawal" (Medical Association of South Africa) was handed out at the initial consultation (Appendix D), the patients also received information on how to take their homoeopathic medication (Appendix E).
- ~ It was advised that smoking cessation take place 1 week to 10 days after the initial consultation.
- ~ A medical and a homoeopathic case history was taken by the researcher and a physical examination performed.
- ~ Each case was repertorised and checked by a qualified homoeopath.
- ~ The isotherapeutic medication and their simillimum or placebo, depending on their allocated group, was dispensed by an independent party and given to the patients the day before smoking cessation. An appointment for 5 days to 1 week following smoking cessation was made.
- ~ On this first follow-up consultation their withdrawal syndrome was assessed and if the patient needed additional medication the prescription was handed to the homoeopathic pharmacist and the medication dispensed according to whether the patient was in the placebo or treatment group.
- ~ The second follow-up occurred one month following the initial consultation where their constitutional medication was re-assessed and any changes in the patients recorded.
- ~ More medication was prescribed according to each individual case and more isotherapy given. This procedure was repeated twice, allowing the experimental phase of the study to run over a period of three months.

3.2 THE SUBJECTS

Thirty participants completed the trial. They responded to advertisements placed in the northern suburbs of Gauteng. Each participant was screened according to a selection criteria: Participants were to be over 18 years of age, smoke 15 or more cigarettes a day for more than a year and be literate to the extent of being able to understand and complete questionnaires. Exclusion criteria included participants with major depressive disorders or those suffering from ulcerative colitis. Patient participation in this study was voluntary, and each had to sign the required patient consent form (Appendix A). They were informed to take the research medication exclusively whilst in the program and were not to include any other intervention.

3.3 INTERVENTIONS

The participants were divided by a random list (the list was drawn up by an independent party). It was a double-blind study where the independent party randomly divided the participants and dispensed the medication accordingly. Each patient received a number on the first consultation, which corresponded to a number on the random list set up by the independent party. Each of these numbers on the list had the corresponding envelope containing a note, which indicated if the patient was to

receive homoeopathic simillimum treatment or placebo treatment. The only person who had access to these envelopes was the independent party. This independent person placed the notes into an envelope before numbering to ensure that even she did not have the knowledge of which patient would receive which treatment.

A medical and a homoeopathic case history was obtained from the patient by the researcher. The case was repertorised, checked and the medication prepared according to the German Homoeopathic Pharmacopoeia (British Homoeopathic Association 1993) by a homoeopathic pharmacist.

The researcher prescribed the indicated remedy (simillimum) for both the treatment and the control/placebo groups and all 30 participants received isotherapy. Due to the remedies being prescribed in an individualistic manner each patient received a different remedy and potency according to the individual's constitution. A wide range of remedies and potencies were used; the basic principle of homoeopathic treatment.

The preparation of isotherapy was from the tobacco of the particular cigarette brand and strength smoked by the individual participants. These remedies were prepared according to the preparation of *Nicotiana tabacum* (British Homoeopathic Association 1993: 693).

3.4 MEASUREMENT

Daily smoking logs and questionnaires were used for measurement (Goldstein 1988).

* **Daily smoking logs**

Appendix C

The participants recorded each cigarette smoked in their daily logs. The number of cigarettes smoked were totalled at the end of the 3 month period.

* **Questionnaires**

Appendix B

Questionnaire on the Health Hazards of Smoking

Part A of the questionnaire assesses the subjects' estimate of reduced life expectancy due to the health risks of smoking. In Part B of the questionnaire the subjects responded to 18 statements which are frequently given as reasons why a person continues to smoke. This questionnaire assesses education as to the health risks of smoking. It is proposed that the less educated the participant, the more difficult he/she will find it to abstain from smoking. Mullen *et al.* 1996 found men with a higher social status (non-manual group) smoked less cigarettes than those in the manual social group. Escobedo *et al.* 1996 showed people with little education as having higher rates of initiating smoking than did those individuals who had more years of schooling.

Questionnaire on Tolerance Dependence

Also known as the Fagerstrom Test for Nicotine Dependence. A high score shows considerable pharmacological tolerance and dependence on nicotine.

Questionnaire on Types of Smoking

Three types of smokers are distinguished by this questionnaire according to the main reason for smoking:

- Habitual-addictive
- Reduction of negative affect
- Positive affect

3.5 STATISTICAL PROCEDURE

- * Since the sample size per group is small ($n_1 = 17$, $n_2 = 13$) non-parametric methods will be used for data analysis.
- * At the end of the 3 months the daily smoking logs of each participant were totalled. The two-sample unpaired t-test was used for data analysis which compared the cigarette consumption between the two groups.
- * The scoring on the questionnaires was calculated and statistically analysed to determine effectiveness of the treatments on certain smoking aspects.

* The Mann-Whitney unpaired two-tailed test was used to compare the 2 groups with respect to several variables of interest. In each case, the null hypothesis states that there is no significant difference between groups 1 and 2 with respect to the variable in charge, at the $\alpha = 0.05$ level of significance. The alternative hypothesis states that there is a significant difference. The Decision rule: the null hypothesis is rejected at the α level of significance if $p \leq \alpha/2$ where p is the observed significance level or P-value. Otherwise, the null hypotheses is accepted at the same level.

* Within each group the Wilcoxon's sign ranked tests were used. In each case the null hypothesis states that there is no significant improvement between the two related samples in the experiment, at the $\alpha = 0.05$ level of significance. The alternative hypothesis states that there is a significant improvement. The decision rule given for the Mann-Whitney tests is used to make decisions. (R.Gulezian 1979.)

* Frequencies, percentages, tables, bar charts and summary statistics will be presented. The statistical package statgraphics version 6+ and SPSS were used for data entry and analysis.

CHAPTER FOUR

RESULTS

4.1 The criteria governing admissibility of the data

Only data from the daily smoking logs and questionnaires collected by the researcher during the trial were used. The consultations and physical examinations were conducted by the researcher. The questionnaires completed at the first and last consultations were accepted. All questionnaires were completed by the participants in this study and were done so in the presence of the researcher. Only participants who recorded their cigarettes smoked and who had taken homoeopathic medication (made according to those principles set out in the Homoeopathic Pharmacopoeia) were accepted into this study.

4.2. Comparison with respect to cigarette consumption between the two groups

4.2.1 Table 4.1

Demographic variables at entry:

	Experimental (n = 17) Mean	Placebo (n = 13) Mean
% Female	70.6 %	84.6 %
Age (years)	35	33
Dependence score (0-10)	5.18	4.77
No. of cigarettes a day	24.11	22.31
Years smoked	20.31	22.52

4.2.2 Table 4.2

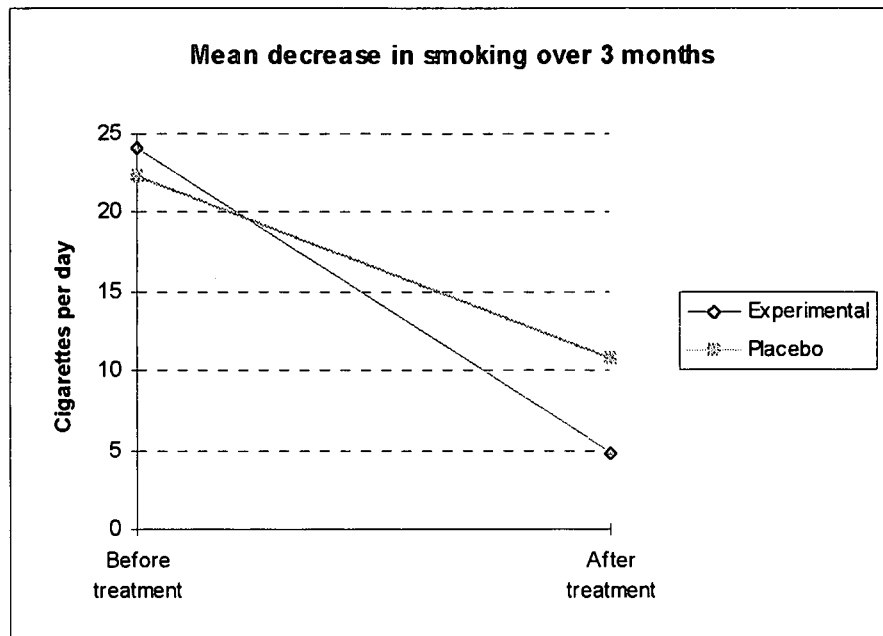
The two-sample unpaired t-test was used for data analysis.

	Experimental group n=17	Placebo group n=13
Average cigarette consumption within 3 months	428.882	973.154
Mean cigarette consumption within 3 months	180	600

P-value = 0.0467729

H₀ is rejected at the $\alpha = 5\%$ level, which concludes that there is a significant difference between groups 1 and 2 with respect to cigarette consumption.

4.2.3 Figure 4.1



In comparing the difference in total abstinence throughout the 3 month period between experimental and placebo groups: 2 out of the 17 subjects of the experimental group ceased to smoke for the entire duration of the trial and 1 out of the 13 subjects out of the placebo group. The difference in cessation rates between the two groups was (11.8 vs 7.7) 4.1 %. On the "slips allowed" criterion defined by Schneider et al. (1996) as any smoking followed by recovery with intent to resume total cessation, 41.2% of the experimental group and 23.1% of the placebo group remained abstinent throughout the 3 months. If these subjects are included in the calculations, experimental and placebo success rates are elevated to 18.1%.

4.3 Comparison of before and after treatments between the two groups with reference to the questionnaires

- * The Mann-Whitney unpaired two-tailed test will be used to compare groups 1 and 2.
- * The Wilcoxon's sign ranked tests will be used to compare related samples within each group.
- * Frequencies and percentages will be presented for each variable of study.
- * A zero score by either group in a particular category is shown as a blank on the graphs.

4.3.1 Questionnaire on Health Hazards of Smoking

Part A of the questionnaire assesses the subjects' estimate of reduced life expectancy due to smoking. The score is obtained by subtracting A1 from A2. A low score of less than 5 years indicates that the participant is underestimating the health hazard of smoking. In Part B of the questionnaire the subjects will respond to 18 statements which are frequently given as reasons why a person continues to smoke. The minimum total score is 0 and the maximum total score 18. A total score higher than 2 indicates an underestimation of the health risks of smoking. Scoring in Part B will be as follows:

Yes / a tick = 1 (if they indorse or go along with the statement)

No / blank space = 0 (if they disagree with the statement or feel that it does not apply to them)

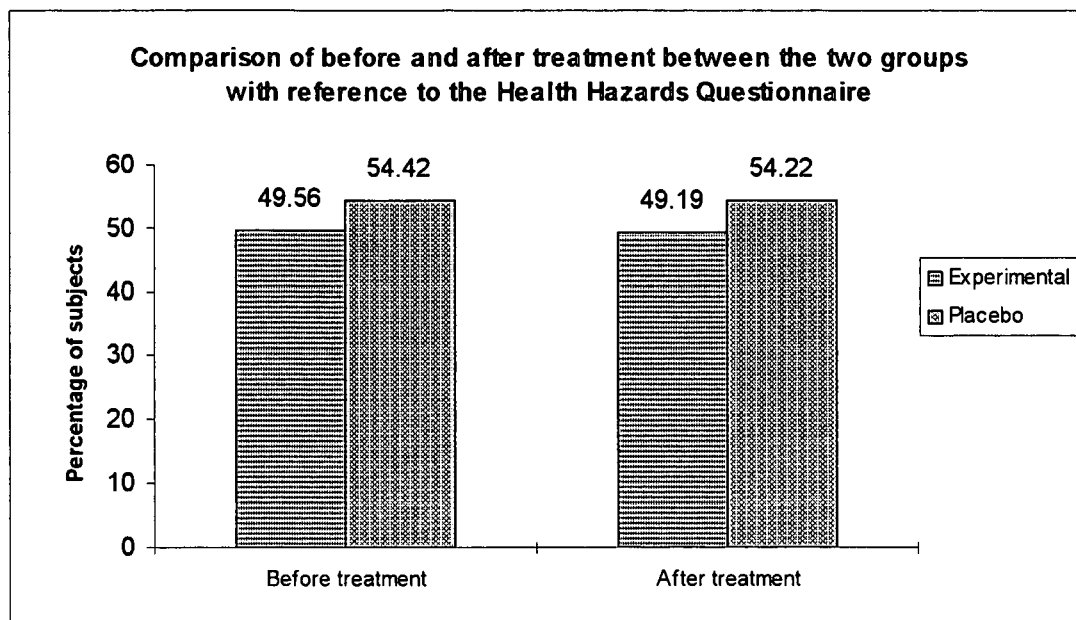
4.3.1.1 Table 4.3

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

Experimental vs. Placebo	Probability value (P)
Before treatment	0.519229
After treatment	0.284498

The P-value for the experimental and the placebo group is greater than 0.05. Thus the null hypothesis was accepted. It was concluded that there was no significant difference in education between the two groups from consultation 1 to 5.

4.3.1.2 Figure 4.2



4.3.1.3 Table 4.4

The mean values of the results of the Wilcoxon's sign ranked tests were calculated and are tabulated below:

Before vs after treatment	Probability value (P)
Experimental	0.6266
Placebo	0.5518

The P-value for the experimental and the placebo group is greater than 0.05. Thus the null hypothesis was accepted. It was concluded that there was no significant difference in education within each group from consultation 1 to 5.

A low score for Part A of this questionnaire indicates a tendency to underestimate the health risks of smoking.

Scoring: 1 = 0 - 5 years
2 = 6 - 10 years
3 = 11 - 15 years
4 = 16 - 20 years
5 = 21 - 25 years
6 = 26 - 30 years

4.3.1.4 Table 4.5

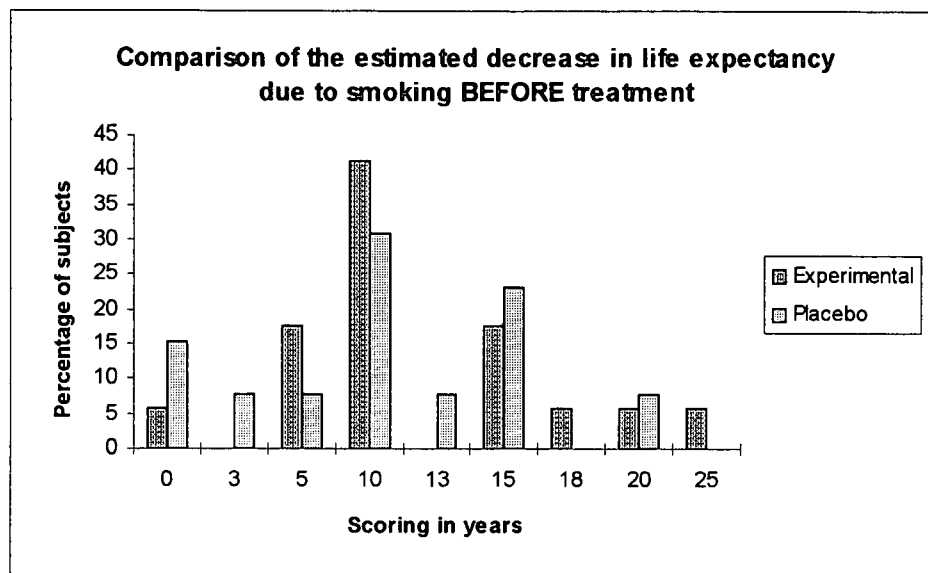
Mean score for each group with regards to reduced life expectancy estimate:

	Before treatment	After treatment
Experimental	2.354	2.764
Placebo	2.129	2.134

Before and after treatment the experimental group had a higher score than the placebo group. The experimental group was thus more aware of the health risks of smoking. Both groups improved slightly in their awareness toward the health risks by the fifth consultation.

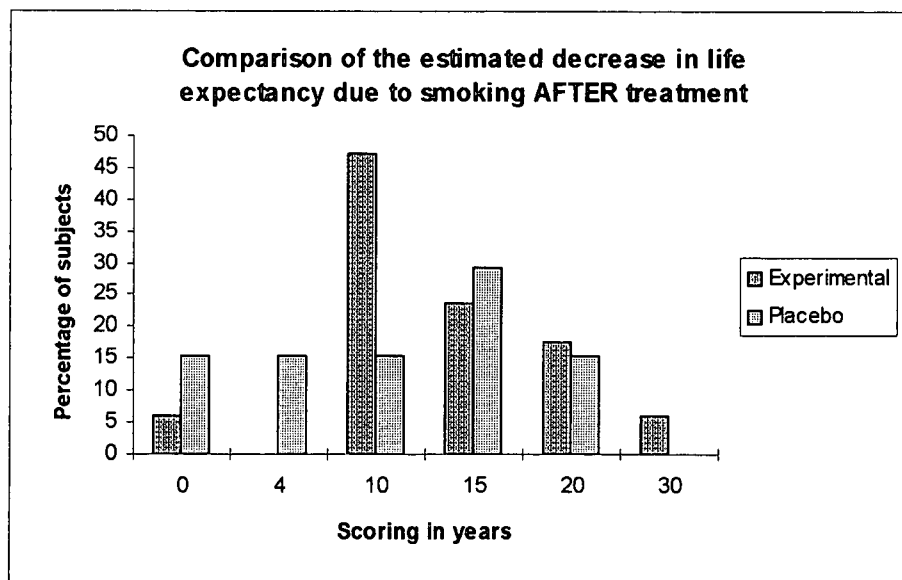
4.3.1.5 Figure 4.3

Part A



4.3.1.6 Figure 4.4

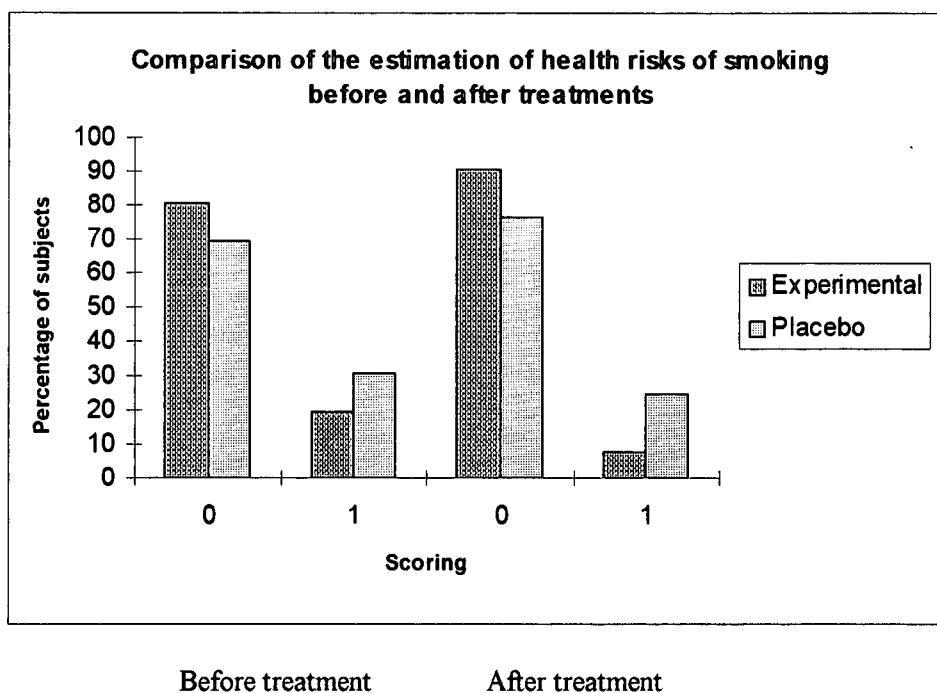
Part A



In Part B a high score is an indication of an underestimation of the health risks of smoking. The experimental group had a lower score than the placebo group. The experimental group thus showed a greater awareness of the health risks of smoking when compared to the placebo group. Both groups had improved slightly in their awareness by the fifth consultation.

4.3.1.7 Figure 4.5

Part B



4.3.2 Questionnaire on Tolerance Dependence

The lowest possible score for this test is 0 and the highest score is 10. A high score shows considerable pharmacological tolerance and dependence on nicotine. Six questions were answered each of which had individual scores ranging from 0 to 3. Mean values for the total scores are shown in fig. 4.6 and individual scoring in fig. 4.7.

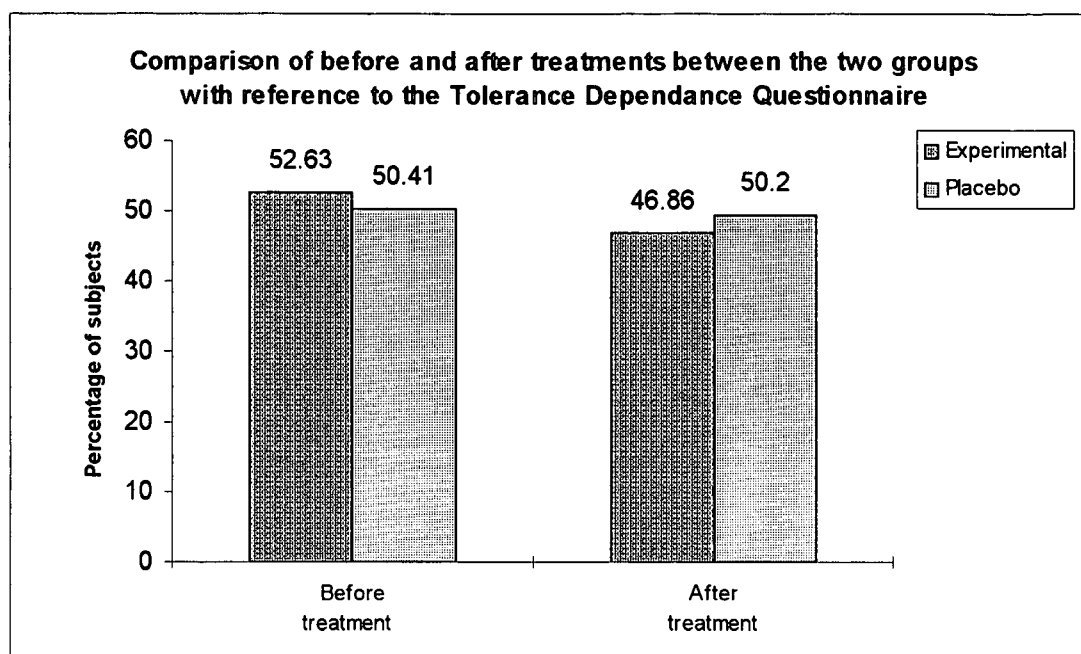
4.3.2.1 Table 4.6

The mean values of the results of the Mann-Whitney U-tests were calculated and are tabulated below:

Experimental vs. Placebo	Probability value (P)
Before treatment	0.595778
After treatment	0.16625

It was found that there was no significant difference between the experimental and placebo group before treatment commenced, however after treatment there was a significant difference between the two groups. In each case: $\alpha = 0.05$ level of significance.

4.3.2.2 Figure 4.6



The experimental and the placebo group were less dependent after treatment. The difference in scores for the experimental group was substantial whereas the placebo group showed less of a decrease in dependence after treatment.

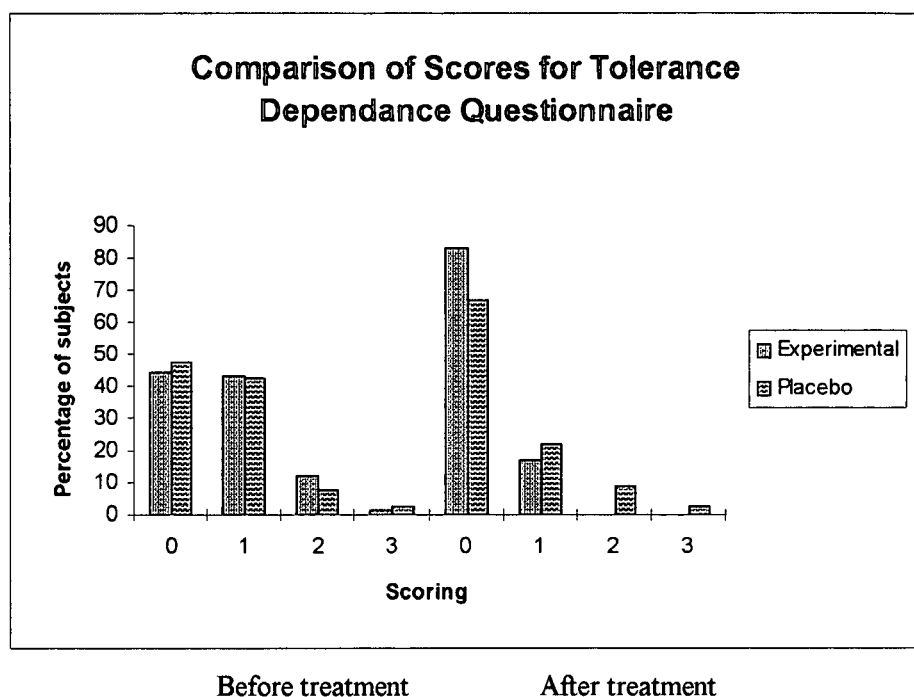
4.3.2.3. Table 4.7

The mean values of the results of the Wilcoxon's sign ranked tests were calculated and are tabulated below:

Before vs after treatment	Probability value (P)
Experimental	0.0197
Placebo	0.2094

The experimental group showed a significant difference from consultation 1 to 5 ($P = 0.0197$). The placebo group showed no significant difference from consultation 1 to 5 ($P = 0.2094$).

4.3.2.4 Figure 4.7



4.3.3 Questionnaire on Types of Smokers

This questionnaire distinguished whether the participant smoked for the:

- * Habitual-addictive affect
- * Reduction of negative affect
- * Positive affect

Each category has a possible maximum average score of 5 and a minimum average score of 1 for that particular reason. (Appendix F)

4.3.3.1 Table 4.8

The mean values of the results of the Mann-Whitney tests were calculated and are tabulated below:

	Experimental vs Placebo	Probability value (P)
Habitual-Addictive Affect	Before treatment	0.562
	After treatment	0.138
Reduction of Negative Affect	Before treatment	0.627
	After treatment	0.323
Positive Affect	Before treatment	0.571
	After treatment	0.242

In each case P is greater than 0.05. The null hypothesis was thus accepted for both groups. It was concluded that there was no difference between the two groups before and after treatment.

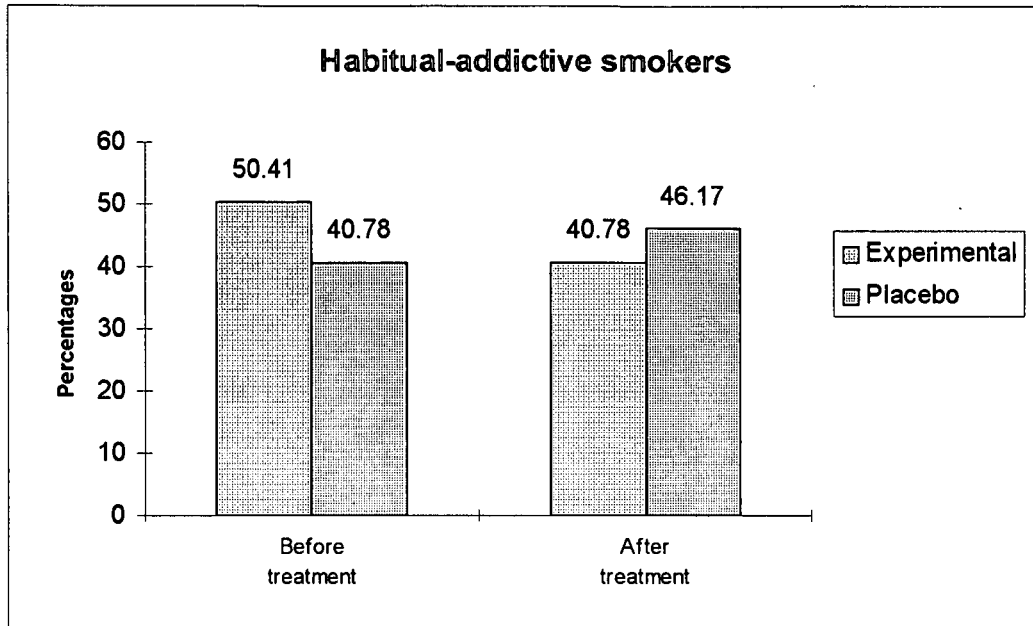
4.3.3.2 Table 4.9

The mean value of the results of the Wilcoxon's sign ranked tests were calculated and are tabulated below:

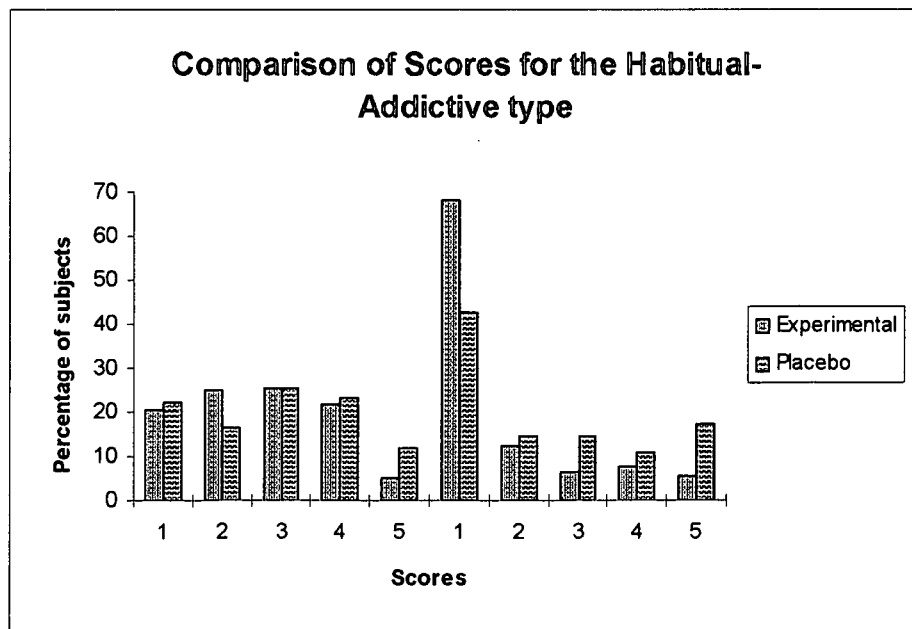
Before vs after treatment	Probability value (P)
Experimental	0.0799
Placebo	0.2392

The null hypothesis was accepted for both groups. It was concluded that there was no significant difference in the Types of Smokers questionnaire within the two groups before and after treatment.

4.3.3.3 Figure 4.8

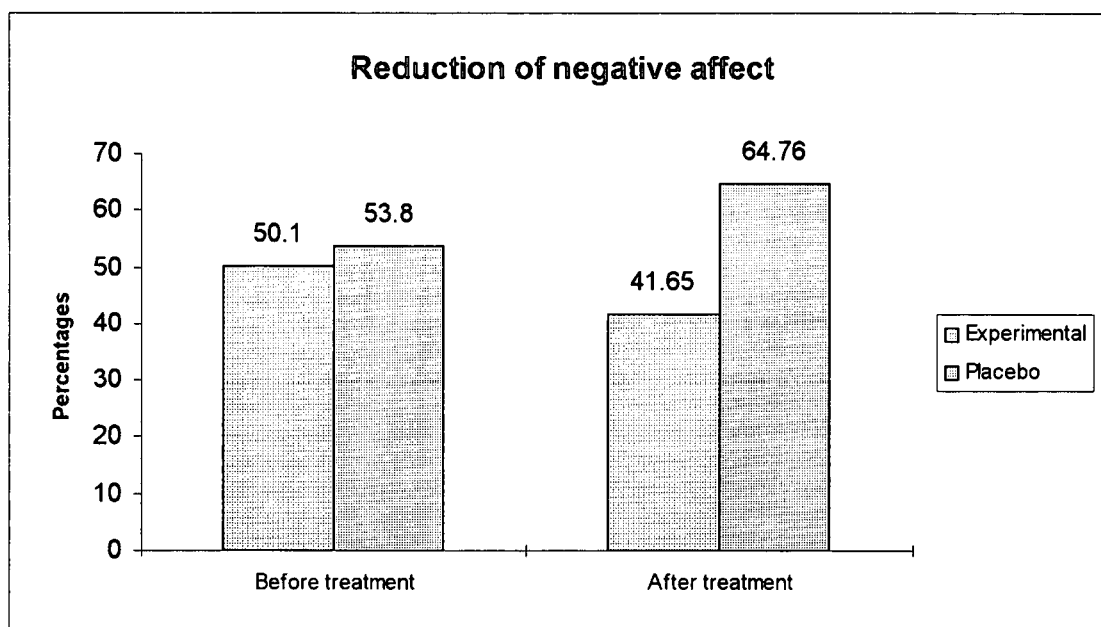


4.3.3.4 Figure 4.9

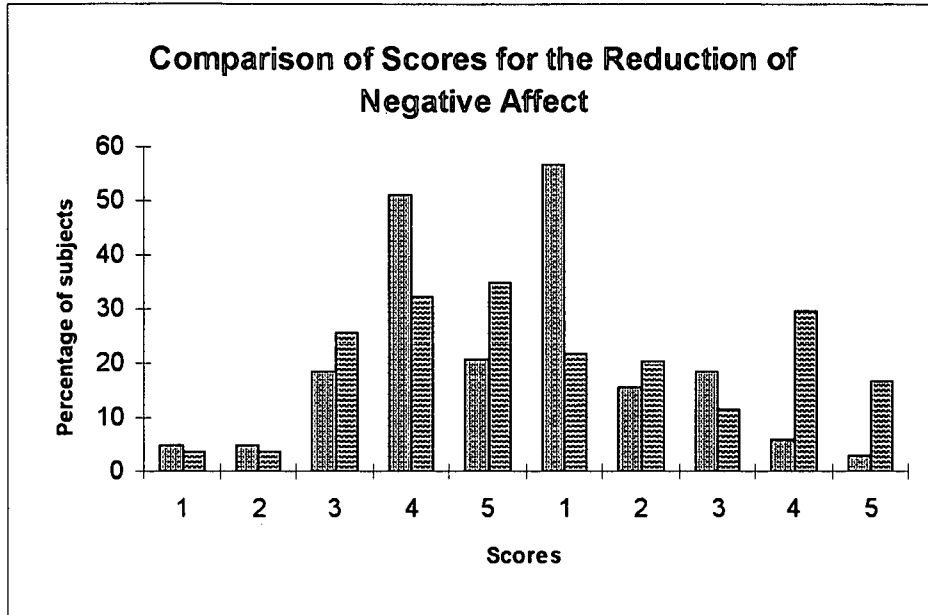


The scoring between the two groups shows that the experimental group had a greater tendency to smoke due to habit than the placebo group before treatment. After treatment however the placebo group were more of the habitual-addictive type. The experimental group smoked less due to habit from consultation 1 to 5. The placebo group smoked more due to habit from consultation 1 to 5.

4.3.3.5 Figure 4.10

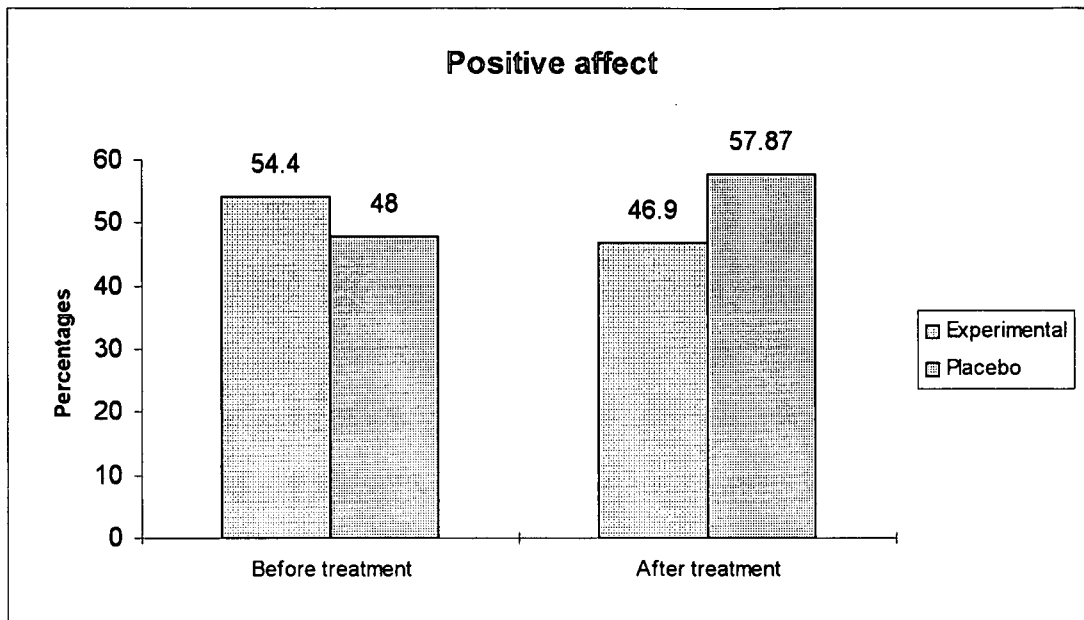


4.3.3.6 Figure 4.11

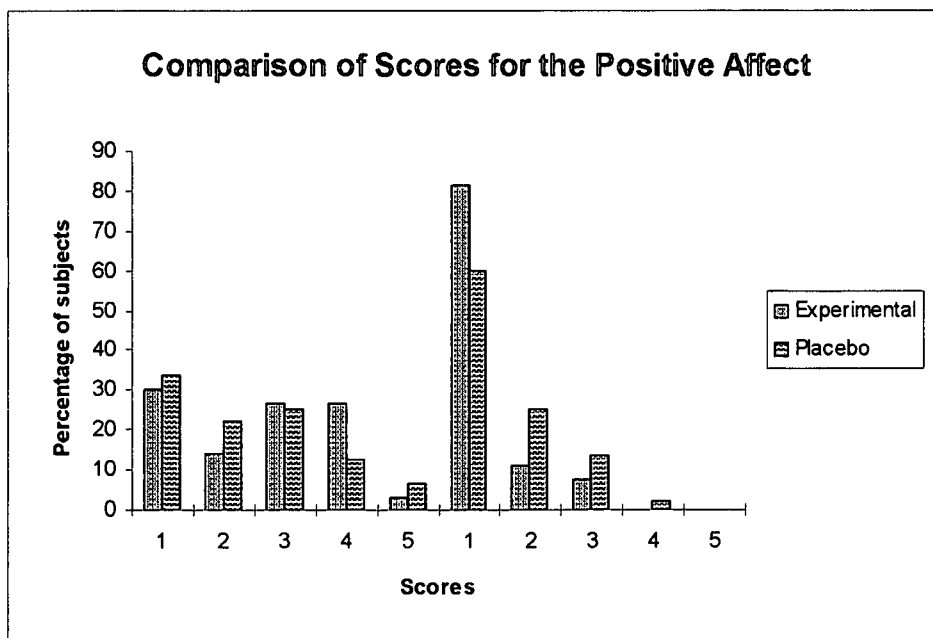


Before and after treatment the placebo group smoked more for the reduction of negative affect than did the experimental group. From consultation 1 to 5 the experimental group smoked less in order to reduce the negative affect. From consultation 1 to 5 the placebo group smoked more in order to reduce the negative affect.

4.3.3.7 Figure 4.12



4.3.3.8 Figure 4.13



The experimental group smoked more for the positive affect than did the placebo group. In comparing the tendencies before and after treatment, the experimental group had less of a tendency to smoke for the positive affect after treatment whereas the placebo has more of a tendency to do so after treatment.

SUMMARY for TYPES OF SMOKERS

In general the experimental group had a greater tendency to smoke for the positive affect or for the pleasure before and after treatment. The placebo group however smoked more to reduce negative aspects before and after treatment.

CHAPTER FIVE

DISCUSSION

In 1994 the World Health Organisation said that in developing countries, per capita consumption of cigarettes had increased by 67% since 1970 (Kingman 1995).

Homoeopathic simillimum together with isotherapy is an effective aid in nicotine dependant smokers who seek help in stopping. The randomised trial of 30 subjects have shown a statistically significant effect. The mean consumption for the experimental group was 24.11 cigarettes per day before treatment commenced and after 3 months of treatment the consumption was reduced to 4.77 cigarettes per day. The placebo group smoked 22.31 cigarettes per day before treatment and 10.81 cigarettes per day after treatment. The daily cigarette consumption decreased by 80.22% in the experimental group and by 51.55% in the placebo group, the difference in efficacy between the 2 groups being 28.66%. The Fagerstrom Tolerance Questionnaire infers nicotine dependence (scoring 1-10) with a high score showing a greater dependence on nicotine. The experimental group, before treatment, had a mean score of 5.18 and after treatment a mean score of 1. The placebo group, before treatment, scored 4.77 and after treatment 2.85. At the end of the treatment the experimental group was thus 80.69% less dependent on nicotine compared to the 35.01% of the placebo group, the difference in efficacy being 45.68%. With regards to

total cessation rates: 2 out of the 17 subjects in the experimental group remained totally abstinent for the entire 3 months (11.8%) and 1 out of the 13 subjects in the placebo group (7.7%). The experimental group showed a 4.1% improvement over the placebo group. If we were to include the "slips allowed" criterion the experimental group rates an 18.1% improvement over the placebo group.

With regards to the 3 questionnaires completed by the subjects no significant difference was found between the 2 groups before treatment (the P-value was greater than 0.05 in each case). After treatment no significant difference in the Health Hazards Questionnaire or in the Types of Smokers Questionnaire was found. The scoring in the Questionnaire on Tolerance Dependence however, showed an overall marked improvement of 45.68% as discussed above. The experimental group was more aware of the health risks of smoking than its counterpart, as was seen in the Health Hazards Questionnaire. The experimental group smoked more for the Positive Affect as was shown by the Types of Smokers Questionnaire. They smoked for the enjoyment, relaxation or stimulation affect. The majority of subjects in the placebo group however smoked more for the Reduction of Negative Affect for whom the cigarette relieved anger, stress, anxiety or depression. For the subjects that continued to smoke, these reasons for smoking remained constant throughout the trial.

Due to lack of counselling in order to minimise variability of the study the education of the subjects on the health risks of smoking was not expected to improve significantly from consultation 1 to 5. The decreases in scores for this questionnaire at consultation

5 was perhaps due to the subjects' rationalising their addictions at the initial consultation which seemed to lessen over the 3 months with their decrease in cigarette consumption. The type of smoker describes a personality type which is not likely to change during the 3 month trial period. The subjects who remained abstinent through the trial found certain parts of the questionnaires to be inapplicable.

Smoking during pregnancy has well-documented adverse effects. Many of the therapies available for smoking cessation are contraindicated in pregnancy. Homoeopathic treatment provides a safer aid to free people from the smoking habit as opposed to the many side-effects experienced from nicotine replacement therapies which have been the focus of research in the last decade.

CHAPTER SIX

CONCLUSIONS AND RECOMMENDATIONS

Managing the tobacco smoking addiction has shown to be more effective when using isotherapy together with the homoeopathic simillimum. A 28.66% improvement in the daily cigarette consumption was evident for the experimental group and a 4.1% improvement in strict abstinence.

Time needs to be spent on smoking counselling for patients entering a homoeopathic practice. The practitioners need to be adequately trained in dealing with substance use disorders, and should be offering advice, encouragement, supervision and support to their patients. Education about the health risks of smoking should be offered in the form of verbal education, pamphlets and perhaps videos. Advice on lifestyle and dietary changes needs to be addressed as weight gain is frequently reported as a factor leading to relapse.

Regarding the questionnaires completed during the trial, a preferred method would be that the Questionnaire on Tolerance Dependence be completed at consultation 1 and 5 only, as opposed to at every consultation and that the Health Hazards Questionnaire and Types of Smokers Questionnaire be completed before treatment only. Many

participants found question 6 of the Tolerance Dependence Questionnaire ambiguous (Goldstein 1988:11-7). This should perhaps have read "Do you smoke so much that you spend the day ill in bed?".

A more objective form of measurement could be implemented in following trials. Salivary cotinine levels or carbon monoxide concentrations in expired air is a way to monitor the effectiveness of treatment. A larger sample group would make the study more viable and due to the high relapse rates in this type of study the trial should, in effect, be carried out over a 1-year period.

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APPENDICES

PATIENT CONSENT FORM

TITLE OF RESEARCH PROJECT _____

NAME OF SUPERVISOR: _____

NAME OF RESEARCH STUDENT: _____

PLEASE CIRCLE THE APPROPRIATE ANSWER:

1. Have you read the research information sheet? YES/NO
2. Have you received satisfactory answers to your questions? YES/NO
4. Have you had an opportunity to discuss 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,
- b.) without having to give a reason for withdrawing, and
- c.) without affecting your future health care.
9. Do you agree to voluntarily participate in this study? YES/NO

SUBJECT NAME _____

(in block letters)

SIGNATURE _____

WITNESS NAME _____

(in block letters)

SIGNATURE _____

RESEARCH STUDENT NAME _____

(in block letters)

SIGNATURE _____

SAMPLE OF QUESTIONNAIRE FOR PARTICIPANTS

DEPARTMENT OF HOMOEOPATHY

CESSATION OF SMOKING: 1997/1998 STUDY

QUESTIONNAIRE ON PERCEPTIONS AND PATTERNS OF SMOKING BY
TOBACCO SMOKERS

INSTRUCTIONS:

Your answers to the questions in this questionnaire will be regarded as strictly confidential and will be used for research purposes only. Please answer the questions as objectively as possible.

Make sure that you answer all the questions and do not skip any by accident. The questions are phrased in such a way that they can be answered by all.

Please read every question carefully before you answer it.

Answer all questions following the instructions given.

The questionnaire should only be completed by the participants in the smoking cessation program.

QUESTIONNAIRE ON HEALTH HAZARDS OF SMOKING

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 than to live five years longer and be unhappy _____
3. I am truly addicted and therefore unable to stop _____
4. 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 been largely 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 of 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 nonharmful purpose in mind _____
17. So smoking proves I am weak-willed. Everybody is entitled to one weakness _____

TOLERANCE DEPENDENCE QUESTIONNAIRE

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?

within 5 minutes

6 – 30 minutes

31 – 60 minutes

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

Yes

No

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

The first cigarette of the morning

Any other

4. How many cigarettes a day do you smoke?

31 or more

21 – 30

11 – 20

10 or less

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

Yes

No

6. Do you smoke if you are so ill that you are in bed most of the day?

Yes

No

QUESTIONNAIRE ON TYPES OF SMOKING

DIRECTIONS: Write down the number allocated to the answer 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 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 realizing 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". _____

DAILY SMOKING LOGS

Date: _____

Cigarette number	Trigger		
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	

COPING WITH WITHDRAWAL

(The Medical Association of South Africa [s.a.] cited by de la Rouviere 1996)

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, deep breathe, etc.
Light headedness and loss of concentration	Probably caused by lack of nicotine	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 mucous	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 exercise (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.

HOW TO TAKE HOMOEOPATHIC REMEDIES:

1. If you are taking powders - just open the one end of the powder and tip it under your tongue. Allow it to dissolve and do not take it with water.
2. If you are taking pills - Do not touch them with your fingers, the pills are dispensed in a glass vial with a plastic lid. Take off the lid and put the desired number of pills in the lid, place pills directly under the tongue, allow them to dissolve.
3. Take your remedies away from meals and avoid eating mint just before or after taking medication. At least 1/2 hour before a meal or one hour after.
4. The remedies must be stored away from CAMPHOR and you must not use any camphor products eg. Vicks products, as these destroy the action of the medicines.

APPENDIX F

METHOD OF SCORING FOR THE QUESTIONNAIRE ON TYPES OF SMOKERS

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	÷ 9	÷ 6	÷ 8
AVERAGE SCORE	=	=	=