

HYPERCHOLESTEROLEMIA

THE ROLE OF HOMOEOPATHY

A dissertation submitted in partial compliance with the requirements for the
Master's Degree in Technology in the Department of Homoeopathy at Technikon
Natal

by

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To whom it may concern

I, Roland Manfred Hillermann, do hereby declare that
this dissertation represents my own work in both
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ABSTRACT

The purpose of this study was to evaluate the efficacy of Taraxacum 5CH in the treatment of hypercholesterolemic patients, in terms of measuring the extent of change in serum total cholesterol (TC), low density lipoprotein (LDL) and high density lipoprotein levels (HDL). The expected result was a resultant lowering of both the TC and LDL levels, as well as an increase of the HDL levels.

Convenience sampling was employed to draw patients from Technikon Natal, a Durban company and the general public from the greater Durban area. Only persons with raised TC and LDL levels were accepted into the trial. Of these one half constituted the control group and received only placebo, the remaining half made up the trial group and were treated with Taraxacum 5CH. The remedies were prepared and dispensed by a qualified pharmacist.

Venous blood was obtained from all subjects before the trial and monthly, for three consecutive months, during the trial. A reputable pathology laboratory was employed to obtain lipogram studies of all blood samples. The participants were asked not to change their then present diets or lifestyles.

Performing paired T-tests on the initial versus the final values of the control group revealed no statistically significant changes in the TC, LDL and HDL levels, whereas in the trial group a significant reduction was computed for the TC and LDL levels, as well as an insignificant increase of the HDL levels. Unpaired T-tests showed that the trial and control groups were not significantly different at the beginning of the trial, but were found to have changed to become significantly different by the end of the trial with respects to TC and LDL levels. The HDL levels were dissimilar initially, but were shown to be significantly similar at the end of the trial.

It would seem that Taraxacum 5CH effected the statistically significant reduction of the TC and LDL levels, as well as the increase of the HDL levels of the trial group, when compared to the control. The medical significance is questionable at this stage, because the extent of the effect of Taraxacum 5CH is not of sufficient clinical significance. It is the researcher's opinion that Taraxacum 5CH could possibly be utilised in the treatment of patients with slightly raised cholesterol levels or to otherwise be combined with other homoeopathic remedies.

UITTREKSEL

Die doel van hierdie studie was om die effektiwiteit van Taraxacum 5CH in die behandeling van pasiënte met hipercholesterolemia te bepaal, deur die verandering van die totale cholesterol- (TC), die laedigheid lipoproteïen-(LDL) en die hoëdigtheid lipoproteïenvlakke (HDL) te bepaal. Die verwagte resultaat was 'n verlaging van die TC en LDL vlakke, asook 'n styging in die HDL vlakke.

Deelnemers vir die studie is by Technikon Natal, 'n firma in Durban en in die Durban gebied gewerf. Slegs persone met, vir hulle ouderdom, verhoogte TC- en LDL vlakke was toegelaat vir die studie. Die een helfte van die kandidate is as kontrolegroep slegs placebo toegedien. Die ander helfte is as eksperimentele groep met Taraxacum 5CH behandel. Die medisyne is deur 'n gekwalifiseerde apteker voorberei en toegedien.

Veneuse bloedmonsters is voor die begin van die studie en daarna maandeliks, vir drie agtereenvolgende maande, geneem en lipogramme daarvan deur 'n bekende patologie- laboratorium bekom. Deelnemers is gevra om nie hulle eetgewoontes en lewensstyle tydens die studie te verander nie.

Statistiese ontleding van die begin- en eindlesings van die kontrolegroep dui daarop dat daar geen betekenisvolle verskil ten opsigte van TC, LDL en HDL waardes is nie. Dieselfde toetse met betrekking tot die eksperimentele groep toon 'n daling van TC- en LDL vlakke wat statisties betekenisvol is, asook 'n statisties onbeduidende styging van HDL vlakke. Tweemonstertoetse wys dat die eksperimentele- en kontrolegroep, in die geval van TC en LDL vlakke, aan die begin van die studie statisties nie betekenisvol verskillend was nie, maar wel aan die einde van die studie statisties van mekaar verskil het. Die HDL vlakke het in die begin statisties van mekaar verskil maar aan die einde was hulle statisties soortgelyk.

Dit blyk asof die behandeling met Taraxacum 5CH 'n vermindering van TC-en LDL-asook 'n styging in HDL vlakke van pasiënte bewerkstellig het. Op hierdie stadium moet die kliniese betekenisvolheid bevestig word, omdat die resultate te min is om van betekenisvolle mediese toepasbaarheid te wees. Dit is die opinie van die navorser dat Taraxacum 5CH moontlik vir pasiënte met matige hipercholesterolemia voorgeskryf kan word, of saam met ander homeopatiese middels gekombineerd vir hierdie doel voorgeskryf kan word.

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CHAPTER ONE

1.1. Introduction

Previous research has shown that hypercholesterolemia increases predisposition to coronary heart disease (Rossouw, *et al*, 1988). High levels of total serum cholesterol, and especially high levels of serum low-density lipoproteins (LDL) have been strongly indicated in atherosclerotic cardiovascular disease and cerebrovascular ischaemia, both these diseases have higher incidences in South Africa than the world mean (Wydham, 1982). According to the National Diet-Heart Study Research Group (1968) there are three major modifiable risk factors that have been identified for these diseases: hypertension, cigarette smoking and hypercholesterolemia. There is a linear correlation between serum cholesterol level increases with the degree of atherosclerosis, and a corresponding regression of the resulting lesion, in the event of cholesterol lowering (Cooper *et al*, 1992). Thus, a reduction of high serum cholesterol levels is desirable in that it reduces the risk of atherosclerotic vascular disease (Holme, 1993).

Classically, should diet and lifestyle modification fail to result favourably, cholesterol - lowering drugs are prescribed, but studies have shown that orthodox treatment has often been found unsuitable in that it illicitly undesirable side-effects and has been indicated in the development of non-hypercholesterolemic health risks (JAMA Council report, 1983). Orthodox drug treatment would be necessary for more than half of South-Africa's adult westernised population should the guidelines of the

American Medical Association be adhered to and would place an intolerable burden on the South-African national health budget (Rossouw et al, 1983).

By determining the efficacy of homoeopathic alternatives, a more cost-effective treatment could be found because, by virtue of their nature homoeopathic medicines have no known side-effects and are less expensive to manufacture than allopathic drugs (Koehnlechner, 1983). Homoeopathy could therefore, in context of the above criteria, possibly offer a viable route of treatment for hypercholesterolemia, if found effective.

1.2. Problem Statement

The purpose of this study is to analyse the effect of Taraxacum 5CH on hypercholesterolemic patients in terms of total serum cholesterol, as well as the low density lipoprotein [LDL] and high density lipoprotein levels [HDL], in order to determine the efficacy of such treatment.

1.3. Hypothesis

It is hypothesised that a significant reduction in both the serum total cholesterol and the LDL levels as well as a significant increase of the HDL levels should occur in the treatment group when compared to the placebo group.

1.4. Delimitations

- A. The homoeopathic remedy utilised in this trial is seen simply in its low potency physiological application and no attempt will be made to include the homoeopathic law of similars or constitutional typologies, neither will a comparison be drawn between homoeopathic and allopathic treatments.
- B. The study shall not attempt to explain mechanisms of medications prescribed.
- C. Factors of lifestyle and diet will be excluded in this trial and are assumed to remain constant in that participants will be asked not to change their diets or lifestyles during the treatment period.
- D. Patients undergoing long-term prescription drug treatment for purpose of cholesterol-lowering shall be excluded from the trial.
- E. Pregnant women may not participate in this trial.
- F. No differentiation will be made between different types of hypercholesterolemia nor will an attempt be made to explain their causes.
- G. Convenience sampling of subjects in the Durban vicinity reduces the possibility of a true random profile sample group.

1.5. Definitions

- Hypercholesterolemia: A medical condition in which a patient's serum cholesterol level exceeds 'normal' or 'desirable' levels.
- Potency (homoeopathic): Potensation consists of two phases:
 - a) dilution and
 - b) succussion or titration.

Original substances or mother tinctures are diluted at either 1 : 10 (X or D potencies) or 1 : 100 (C potencies), i.e. a 1 : 100 dilution would be a 1CH, repeating the procedure three times would yield a 3CH potency. The suffix 'H' in 5CH indicates a "Hahnemannian" potency, i.e. produced according to rules laid down by Hahnemann (Diamantidis, 1986).

1.6. Assumptions

It is assumed that

- A. all blood samples will be treated equally.
- B. the test results from the laboratory will be accurate.
- C. the subjects of this trial will not significantly change their diet or lifestyle.
- D. patients will take medication as prescribed.
- E. patients will observe fasting guidelines.
- F. all medication will be manufactured according to the Homoeopathic Pharmacopoeia.

CHAPTER TWO

2.1. Introduction to Related Literature

The subject of cholesterol levels and their effects on vascular disease, especially on atherosclerotic cardiovascular disease, has been widely researched over the last few decades and has been the cause of much controversy and debate amongst medical scientists and physicians (Dock, 1990). To date many aspects of hypercholesterolemia have been researched and explained and many factors have now been agreed upon as being a scientific basis for clinical research (JAMA Council Report, 1983).

According to the National Diet-Heart Study Research Group (1968) an elevated level of total serum cholesterol, or hypercholesterolemia, is one of three major modifiable risk factors of atherosclerotic cardiovascular diseases. This group of diseases has a particularly high incidence in South Africa with highly debilitating and often fatal consequences, which in turn has numerous social implications and gives rise to various economic effects (Rossouw et al, 1983).

The JAMA Council report (1983) discusses that cholesterol reducing drugs are available but do elicit side-effects when taken long-term. The homoeopathic route may offer an inexpensive alternative without undesirable side-effects, but a need exists to expand on this field of research, although some work has been done in the past (Metzger, 1977; Julian, 1979; Jouanny, 1984).

2.2. Demographics

Statistics have clearly shown that fatality and debility caused as a result of atherosclerotic cardiovascular diseases is on the increase all over the world and that the Republic of South Africa is no exception by having one of the highest incidences of these diseases in the world (Wydham, 1982). The most significant amongst these diseases is ischaemic heart disease leading to myocardial infarctions, which, according to Rossouw et al (1983), is the most common cause of death amongst white South African males. It affects 240 per 100 000 white males and 85 per 100 000 white females per annum with the figures for Asians being similar and those for Coloureds and Blacks, although lower, are steadily rising as these population groups adapt to westernised life-styles (Wydham, 1982). The resulting strain on the economy through lost man hours, cost of medication and disability compensation gives rise for concern (Rossouw et al, 1988).

2.3. Risk Factors

In a study conducted by the National Diet-Heart Study Research Group (1968), it was found that major modifiable risk factors indicated in atherosclerotic cardiovascular disease include: hypertension, cigarette-smoking and hypercholesterolemia. The study also found that lesser risk factors include inactivity, diabetes mellitus, obesity, hyperuricemia and coronary-prone behaviour and concludes that there is an evident need to modify these risk factors as a preventative measure against cardiovascular diseases. Reducing serum cholesterol levels is possible, to a certain extent, by means of life-style modifications, such as low-cholesterol diets, quitting smoking, regular aerobic activity and reducing stress-levels (JAMA Council report, 1983).

2.4. Diet Factors

Dietary guidelines typically include recommendations with regards to decreasing intake of saturated fats and increasing polyunsaturated fat intake, increasing vegetable and monosaturated oil consumption and incorporating a high fibre component in the diet (JAMA Council report, 1983). The National Diet-Heart Study Research Group (1968) achieved a reduction of only 10% to 12% in patients subjected to diet treatment showing that only a slight reduction in serum total cholesterol level may be achieved by following diet regimes. Taking into consideration that the liver synthesises approximately 80% of the serum cholesterol (+/- 800 mg per day) and that only the remaining 20% is derived directly from the diet (Meyer BJ, 1983) it becomes evident that, although dietary modification may to an extent be suitable, a greater impact could probably be achieved by controlling cholesterol production or modifying the cause of the excessive production rate.

2.5. Risk Levels

An 'ad hoc' committee of the South African Heart Foundation has recommended guidelines for the medical profession which depict ranges for 'high risk', 'medium risk' and 'desirable' levels. In these guidelines 'medium risk' has been defined as total serum cholesterol levels at 5,2 - 6,2 mmol/l and 'high risk' levels at above 6,2 mmol/l (Meyer BJ, 1983). Rossouw *et al* (1988) point out that these guidelines are on par with those of the European Atherosclerotic Society, the British Cardiac Society, the National Institute of Health of the United States of America and the National Cholesterol Education Program Adult Treatment Panel.

In recent studies (Davies *et al*, 1989; Pekanen *et al*, 1990) it was found that in only about 50% of deaths due to coronary cardiovascular disease were serum cholesterol levels found to be in the 'high risk' category. The studies discuss that a discrepancy exists, as to which levels are desirable, since the mortality levels from atherosclerotic heart disease is high even in cases with serum cholesterol levels within the normal or moderate risk ranges and imply that hypercholesterolemia is not singly the cause of atherosclerotic heart disease and that non-hypercholesterolemic causes play additional roles in the development of such diseases.

A council report by the American Medical Association (JAMA Council Report, 1983) cites that various authorities have been of differing opinions regarding the efficacy of dietary and pharmacological therapies in altering blood cholesterol concentrations. In the report it is suggested that current drug therapies should only be pursued, should dietary and weight-loss regimes be unsuccessful, and that such therapies should be undertaken for a life-time. The report also cautions that it should also be taken into account that pharmacological therapies may have undesirable side-effects.

2.6. *Allopathic Drugs*

Rossouw *et al* (1983) argue that if the guidelines laid down by the American Multiple Risk Factor Intervention Trial Research Group that suggest drug treatment for all patients with total serum cholesterol levels above 6,3 mmol/l would be enforced in South Africa, it would result in approximately half the adult white and Asian male population needing drug treatment for hypercholesterolemia and that this would financially overburden the national health care system.

According to MIMS Medical Specialities (1994), the most commonly prescribed drugs presently for cholesterol reduction are of three basic groups:

1. Bile acid binding resins: these drugs lower total cholesterol and LDL levels. The side-effects listed are gastro-intestinal symptoms, gallstones, bleeding tendency, increased level of transaminases and increased absorption of folic acid, warfarin, digitoxin, thyroxin and others.
2. Hydroxymethyl CoA reductase inhibitors: this group of drugs most effectively reduces LDL levels and also slightly increases HDL levels. Side-effects include gastro-intestinal symptoms, muscle weakness, skin rashes, hair-loss, blood discrasias and constipation.
3. Nicotinic acid: this drug inhibits LDL synthesis and decreases HDL catabolism. Side-effects are gastro-intestinal symptoms, fatigue, cardiac symptoms, flushing and hyper-uricemia.

In a study conducted by Holme (1993) utilising collective data accumulated over the last twenty years, it is clearly demonstrated that the lowering of circulating total cholesterol and especially LDL's can arrest and, in some cases, reverse coronary atherosclerosis. Conversely, higher levels of high-density lipoprotein cholesterol

(HDL) are in inverse proportion to subsequent coronary events (Pekanan et al, 1990). These aspects have been widely researched and documented and are therefore considered excessive within the framework of this study.

These claims are in contrast with the studies by Davies, et al. (1989) and Pekanan et al. (1990) but taken together, they might support the claim of Reckeweg (1986), who suggests that hypercholesterolemia is a symptom of one or more underlying causes of atherosclerotic heart disease. It therefore becomes evident that research in the field of hypercholesterolemia and atherosclerotic disease has by no means been exhausted.

2.6. *Taraxacum*

Taraxacum autumnale is commonly known as the dandelion. Other botanical names are Leontondron taraxacum and Dens leonis. It is a perennial, deciduous Herb and flowers from mid-spring until autumn. It grows in temperate to alpine climates and should be gathered as a whole plant in the pre-flowering stage to prepare the mother tincture (Battacharyya, 1980). Taraxacum autumnale contains a number of physiologically active substances, including choline, inosite, taraxacerin, inoline and Vitamin D (Julian, 1979).

The first experiments with Taraxacum autumnale date back to Hahnemann and subsequent studies were conducted by Gutman, Langhammer and Pischel (Gutman, 1956; Julian, 1979; Metzger, 1977; Pischel, 1955) who all recorded the beneficial effects of Taraxacum on liver de-toxification.

Taraxacum is commonly prescribed as a homoeopathic remedy to stimulate liver de-toxification when the diagnosis and the symptomology warrant its application (Julian, 1979). It may be prescribed alone or in conjunction with other remedies that are typically prescribed for patients with hepatic conditions and insufficiencies (Jouanny, 1984; Julian, 1979).

Maury (1965) and Jouanny (1984) suggest the prescription of Taraxacum as a drainage remedy along with generally prescribed liver treatments. It should be given for its beneficial effects of stabilising hepatic physiology.

It is in the light of the fact that Taraxacum autumnale is generally being prescribed in homoeopathic potency as a liver drainage remedy, that the researcher considered the possibility of this remedy having an effect on the liver's metabolism of cholesterol. The 5CH potency was chosen as a low potency to accentuate the effect of the remedy in its physiological application, i.e. to have a physical effect rather than higher potencies, where the constitution of the patient would have been of greater significance (Diamantidis, 1986).

CHAPTER THREE

3.1 *The data*

- A. This trial was the only source of data.
- B. The trial was carried out only on subjects meeting the necessary requirements:
 - a) Persons that had serum total cholesterol levels within the 'medium risk' and 'high risk' categories (Meyer BJ, 1984).
 - b) Pregnant women were excluded from this trial, since it is known that during pregnancy a transient hypercholesterolemia may develop (Cooper et al. 1992).
 - c) Persons with a history of surgery or a myocardial infarction within the previous month were excluded, because such events may influence cholesterol levels (Cooper et al. 1992).
 - d) Persons on cholesterol-reducing medication were deemed unsuitable for the trial for obvious reasons and were not accepted.
- C. Blood samples were
 - a) all analysed at the same, reputable laboratory.
 - b) taken by a registered nurse in the presence of the researcher or at the pathology laboratory itself.
 - c) taken in the morning after an overnight fast (it was recommended to all patients to only take water after seven o'clock in the evening, thus ensuring a minimum fasting period of 12 hours).

3.2 Research Methodology

Participants were selected by means of convenience sampling and were approached by various means of advertisement within the greater Durban area. A letter was posted to all Technikon Natal staff, an advertisement placed in a local newspaper, several companies were approached and a stand was set up at an 'open day' of the South African Cancer Association. Free cholesterol tests were offered to all interested persons. All respondents were screened for elevated total cholesterol levels by using a Boehringer Reflotron. A basic interview was conducted with each potential subject regarding conditions of the trial to ensure exclusion of subjects outlined under the heading 'delimitations'.

Respondents falling within the 'medium' and 'high risk' categories were then asked to participate in the trial and venous blood samples were taken after an overnight fast. Blood samples were taken by registered nurses with the patient seated and excessive venostasis avoided. Clear Venoject tubes were used and the pathology laboratory utilised the Technicon method (Allain *et al.*, 1974; Lie *et al.*, 1976) to determine lipid profiles. Only respondents with elevated total cholesterol and LDL levels were selected to commence in the trial. 23 participants of the trial group and 18 of the placebo group completed the experiment, i.e. the sample size amounted to 41 subjects.

Selected patients were briefed on the guidelines of taking homoeopathic medicine and were instructed to dissolve five pills under the tongue twice daily, on waking and at bedtime. A qualified pharmacist then dispensed the medication, Taraxacum 5 CH, on a randomised double blind basis. Patients were requested to return at monthly intervals for three consecutive months for further blood tests, and were advised not to change their lifestyles, diets or exercise routines.

A further three blood tests were then performed at monthly intervals, all at the same pathology laboratory. Lipid profiles were obtained in order to establish changes in the total cholesterol, LDL and HDL levels.

CHAPTER FOUR

4.1. Statistical analysis of the results

4.1.1. Total Cholesterol Levels

Table 1 - Initial reading, unpaired T-Test

Group	M	95% CL	SL	t
Trial	6.84	-0.751 ; 0.946	0.818	0.232
Control	6.75	-0.751 ; 0.946	0.818	

M = Mean total cholesterol level

CL = Confidence interval

SL = Significance level

t = Computed t-statistics

The computed statistics thus indicates that no significant difference exists between the initial trial and control groups.

Table 2 - Final reading, unpaired T-test

Group	M	95% CL	SL	t
Trial	6.75	-0.643 ; 0.764	0.863	0.1733
Control	6.70	-0.643 ; 0.764	0.863	

M = Mean total cholesterol level

CL = Confidence interval

SL = Significance level

t = Computed t-statistic

The final readings show an increased difference between the mean levels.

Table 3 - Paired T-tests comparing initial / final TC readings

Group	MD	SD	95% CL	SL	DOF	t
Trial	0.14	0.445	-0.317 ; 0.140	0.425	22	0.818
Control	0.07	0.488	-0.168 ; 0.165	0.627	17	-0.493

M = Mean difference

SD = Standard deviation

CL = Confidence interval

SL = Significance level

DOF = Degree of freedom

t = Computed t-statistic

The initial and final readings of the control group thus do not differ significantly, whereas the difference in the trial group is statistically significant.

4.1.2. LDL Levels

Table 4 - Initial reading, unpaired T-test

Group	M	95% CL	SL	t
Trial	4.68	-0.801 ; 0.819	0.981	0.023
Control	4.46	-0.801 ; 0.819	0.981	

M = Mean LDL level

CL = Confidence interval

SL = Significance level

t = Computed t-statistic

The difference between the means is statistically significant for the initial LDL levels.

Table 5 - Final reading, unpaired T-test

Group	M	95% CL	SL	t
Trial	4.45	-0.948 ; 0.432	0.453	0.758
Control	4.47	-0.948 ; 0.432	0.453	

M = Mean LDL level

CL = Confidence interval

SL = Significance level

t = Computed t-statistic

The computed statistics indicates no significant difference between the trial and control groups and the final readings.

Table 6 - Paired T-tests comparing initial / final LDL readings

Group	MD	SD	95% CL	SL	DOF	t
Trial	0.21	0.622	-0.476 ; 0.075	0.144	22	1.515
Control	0.03	0.352	-0.114 ; 0.248	0.778	17	0.448

M = Mean difference

SD = Standard deviation

CL = Confidence interval

SL = Significance level

DOF = Degree of freedom

t = Computed t-statistic

This table depicts that there is no significant change in the initial vs. the final LDL readings of the control group, but shows a significant difference in the trial group readings.

4.1.3. HDL Levels

Table 7 - Initial reading, unpaired T-test

Group	M	95% CL	SL	t
Trial	1.195	-0.327 ; 0.156	0.479	0.714
Control	1.39	-0.327 ; 0.156	0.479	

M = Mean HDL level

CL = Confidence interval

SL = Significance level

t = Computed t-statistic

Thus, the HDL-level of the trial and control group were significantly different before the trial.

Table 8 - Final reading, unpaired T-test

Group	M	95% CL	SL	t
Trial	1.31	-0.399 ; 0.143	0.346	-0.956
Control	1.37	-0.399 ; 0.143	0.346	

M = Mean HDL level

CL = Confidence interval

SL = Significance level

t = Computed t-statistic

The results show that the HDL levels of the trial and control group did not differ significantly at the close of the experiment.

Table 9 - Paired T-tests comparing initial vs. final HDL readings

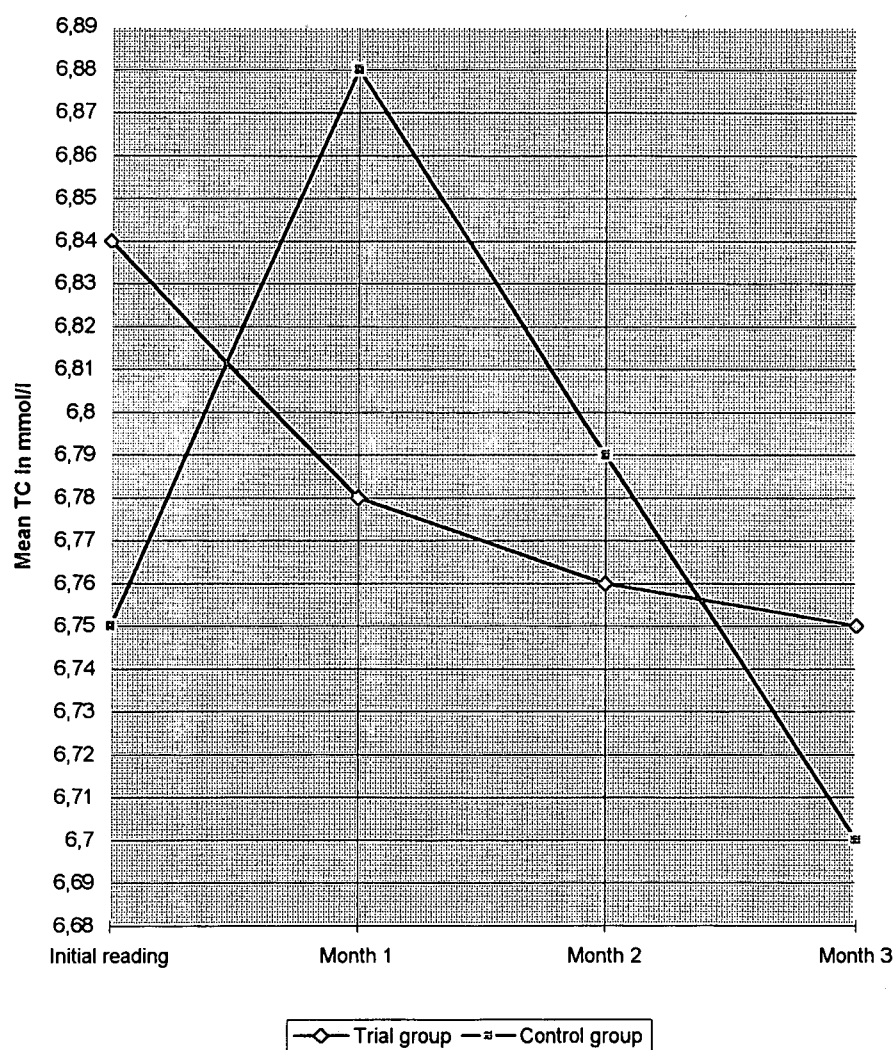
Group	MD	SD	95% CL	SL	DOF	t
Trial	0.07	0.23	0.002 ; 0.199	0.049	22	2.07
Control	0.035	0.085	0.012 ; 0.102	0.017	17	2.677

- M = Mean difference
- SD = Standard deviation
- CL = Confidence interval
- SL = Significance level
- DOF = Degree of freedom
- t = Computed t-statistic

Although both the trial and control groups' HDL levels did not change significantly, the trial group had a slight, if not significant improvement over the control group.

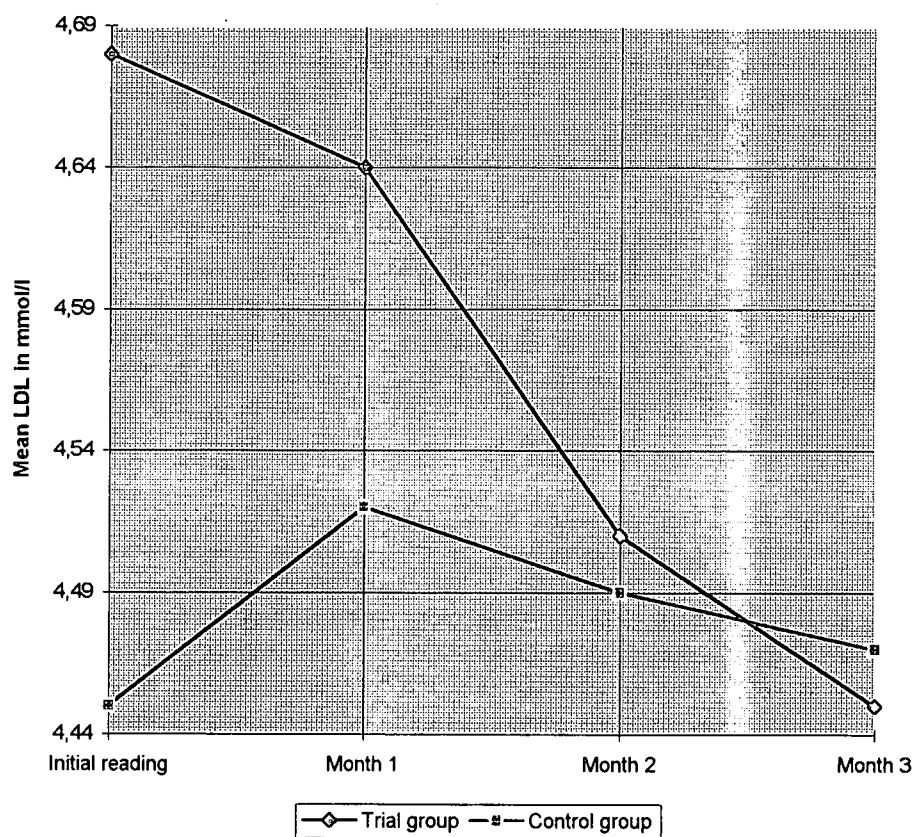
4.3.1. Figure one

Figure 1: The mean TC levels of both trial and control groups before the trial and on months 1, 2 and 3



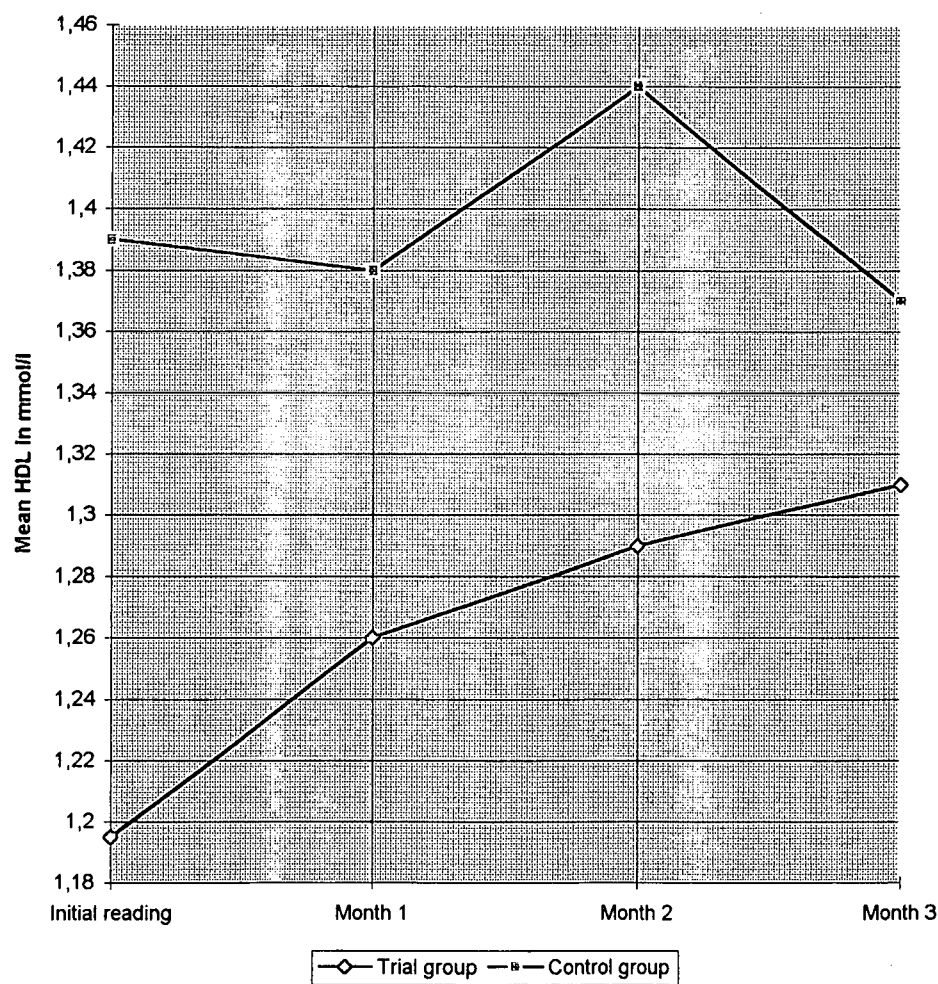
4.3.2. Figure two

Figure 2: The mean LDL levels of both trial and control groups before the trial and on months 1, 2 and 3



4.3.2. Figure three

Figure 3: The mean HDL levels of the initial trial and control groups as well as the repective monthly readings over three months



CHAPTER FIVE

5.1. *Evaluation of the Results*

5.1.1. Introduction

Comparing the trial and placebo groups by means of applying unpaired T-tests, the initial mean values of the total cholesterol were calculated to be statistically similar, giving a platform for reasonable comparison, although the initial LDL and HDL values were shown to be statistically dissimilar. Comparing beginning and end readings of the trial group showed that both the total cholesterol and the LDL levels showed a decrease that was statistically significant, and the HDL levels showed a statistically insignificant increase, and that the readings of the placebo group, although they showed similar tendencies, were not marked enough to be of statistical significance.

5.1.2. Total Cholesterol Levels

Applying unpaired T-tests on the initial trial and placebo readings of total cholesterol resulted in a computed t-statistic of 0.232 at a significance level of 0.818, thereby indicating that the researcher should not reject the nil hypothesis that the two groups are statistically similar; the medians being 6.75 mmol/l and 6.64 mmol/l, respectively. Applying the same hypothesis test to the last total cholesterol readings gives a t value of 0.173 and a significance level of 0.863 indicating that the difference between the groups had not developed a significant difference over the course of the trial and that, as is demonstrated by the graph (4.3.1. Figure one), that there is a slight convergence between the graphs of the mean TC levels of the trial and placebo groups. The respective medians for the end readings being 6.75 mmol/l and 6.70 mmol/l. Paired T-tests showed a significant reduction of the TC levels of the trial group ($t = 0.818$), but not in the control ($t = 0.493$).

5.1.3. LDL Levels

Similarly, applying unpaired T-tests on the initial trial and placebo readings of the LDL levels resulted in a computed t statistic of 0.023 at a significance level of 0.981, thereby calculating that the nil hypothesis should be rejected and that the two groups are statistically similar. The initial mean of the trial group was higher than the control, at 4.68 mmol/l (vs. 4.46 mmol/l) but had improved to 4.45 mmol/l (vs. 4.47 mmol/l) by the end of the trial, by which time the trial and control groups had become statistically similar; with $t = 0.758$, at a significance level of 0.453.

The trial group performed favourably against the control during the trial, and when end results were compared with initial readings and showed a significant drop in LDL readings ($t = 1.515$; significance level: 0.144), whereas the control group remained relatively unchanged ($t = 0.448$; significance level: 0.778). This indicates a greater improvement of LDL levels in the trial group when compared to the control group.

5.1.4. HDL Levels

Using similar hypothesis testing on the results of the HDL levels, concluded in rejecting the nil hypothesis for the initial test figures and accepting that the means of these groups were statistically dissimilar, the mean levels of 1.195 mmol/l for the trial, and 1.39 mmol/l for the placebo groups. ($t = 0.714$ and the significance level calculated to 0.479). The final HDL readings showed the median of the HDL levels in the trial group to have risen to 1.31 mmol/l and the median of the placebo group to actually have slightly decreased to 1.37 mmol/l. At the close of the trial both groups were computed to be statistically similar ($t = 0.956$; significance level: 0.346). On the graph (Fig. Two) it can be seen that the values of the trial group had increased towards the end of the trial to almost match those of the control, of which the levels had remained more constant.

Unpaired T-tests showed that mean HDL levels of neither the trial group nor the control changed significantly over the course of the trial ($t = 2.07$ and 2.677 ; significance level: 0.049 and 0.017, respectively), although the HDL levels of the trial group showed a slight improvement over the control on the graph (Fig. three).

5.2. Discussion

Viewed in the light of the hypotheses, the trends of the results of the trial were shown to be favourable. Compared to the values of the placebo group, the total cholesterol and LDL levels of the trial group decreased significantly and the HDL levels showed an increasing trend. These trends, as shown on the graph indicate clinically desirable tendencies.

The reliabilities of these results may have been influenced by various factors:

- Firstly, many of the participants of the trial may have become aware of their hypercholesterolemic condition for the first time after the screening test and although asked not to modify diet or lifestyle, may have made some adaptations.
- Secondly, although all participants were requested to strictly adhere to the fasting rules laid down, one can with reasonable certainty assume that these were not always carried out.
- Thirdly, there is no way of confirming that all participants took their medication as prescribed, some admitting that they had occasionally forgotten.

All of the above factors may have played a role in altering the blood lipid profiles in some way to jeopardize the accuracy of the results.

Notwithstanding these factors, one might accept that, should any of the abovementioned irregularities have occurred, the probability of occurrence within both trial and placebo groups is equal. Therefore statistical differences that may have been caused may be assumed to be insignificant.

At this point, a brief mention should be made of the results of allopathic drug therapy trials. A collection of data of drug therapies by the American Medical Association indicates that desirable lipid profiles were achieved by most drug therapies even in subjects within the high risk category (JAMA Council Report, 1983).

Taraxacum 5CH may, in the light of comparisons with allopathic drug treatments, seem less effective in the treatment of hypercholesterolemia. It may as a result of further research become suitable in treating patients with mildly elevated cholesterol levels when the trends of this trial are taken into account.

CHAPTER SIX

6.1. *Conclusion and Recommendations*

This trial has demonstrated that Taraxacum 5CH has a statistically significant level of efficacy in the treatment of hypercholesterolemia. The decrease of the TC levels as well as the LDL levels of the trial group were statistically significant in comparison with the control, and, although the HDL levels did not show significant changes, the levels of the trial group did increase slightly, whereas those of the control group remained almost constant.

In order to fully assess the efficacy of Taraxacum as a possible treatment for hypercholesterolemia, the researcher recommends that further research should be done using Taraxacum possibly over a longer period of time or alternatively in conjunction with other remedies, especially remedies with a strong hepatic affinity, for example, *Calcarea carbonica*, *Lycopodium clavatum* or *Nux vomica*. Furthermore, Taraxacum could be researched comparing a number of different Hahnemannian or other types of potencies.

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