

**THE HOMOEOPATHIC SIMILLIMUM TREATMENT OF ACUTE ARTHRITIS IN
PRIMARY GOUT IN TERMS OF THE ILLNESS INTRUSIVENESS SCALE,
BLOOD URIC ACID LEVELS USING THE URICASE CONVERSION METHOD
AS WELL AS THE ACUPULSE HOMEOSTAT MACHINE**

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Master's degree in Technology in the Department of Homoeopathy at Technikon
Natal.

I, Henriette Smulders, do hereby declare that this dissertation represents my own
work in both conception and execution.

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DEDICATION

I would like to dedicate this dissertation to my family and friends for their continuous love, support and encouragement.

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ABSTRACT

The aim of this placebo-controlled study was to investigate the homoeopathic simillimum treatment of acute arthritis in primary gout in terms of the illness intrusiveness scale, blood uric acid levels using the uricase conversion method as well as the Acupulse Homeostat machine.

For this study 30 patients suffering from primary gout were required. The patients were obtained by advertising in local newspapers and at retirement homes.

Patients were included in the study if they presented with six of the seven criteria taken from the American Rheumatism Association's criteria for acute arthritis of primary gout. The patients were randomly divided into two groups: a treatment group, receiving homoeopathic simillimum treatment and a control group, receiving a placebo. Two follow-up consultations were scheduled at two week intervals.

Data was obtained by means of a questionnaire (completed by the patient), readings from the Acupulse homeostat machine and a blood uric acid test. This data was collected at all three consultations. Data entry and analysis was done using the SPSS statistical package.

Due to the small sample size, data obtained from the questionnaire was statistically analyzed using non-parametric methods. The Mann-Whitney Unpaired Test was done to compare the treatment and placebo groups. Results showed that there was no significant difference between the groups. The Wilcoxon's Signed Rank Test was done to compare data within groups. The only significant difference was found within the treatment group between the first and second consultations as well as the first and third consultations. There was significant improvement with regard to *active recreation*. The tests were performed at $\alpha = 5\%$ level of significance.

Data obtained from the Acupulse Homeostat machine as well as the blood tests were analyzed using parametric tests because of the fact that they were continuous variables (regardless of the small sample size per group). In the case of both variables, comparison between the treatment and placebo group was made using the Two-Sample Paired T-Test and comparison within groups

was made using the Two-Sample Unpaired T-Test. No significant difference was found between any of the groups. These tests were performed at $\alpha=5\%$ level of significance.

Blood uric acid levels increased at the third consultation, indicating a possible mobilization of uric acid. This reaction is similar to the reaction that is found when patients start conventional chronic prophylactic treatment.

Comparison between the data obtained from the Acupulse Homeostat machine and the blood test showed a correlation in the general trend although there was no correlation between values. This indicates that although the Acupulse Homeostat machine may be useful in detecting abnormalities, it is not specific enough to replace blood tests as a diagnostic tool.

On the whole there was an improvement in the condition of all the patients and it is believed that further studies will confirm these positive results.

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DEFINITION OF TERMS

Bifringent: 'The quality of transmitting light unequally in different directions; double refraction.'

(W.B. Saunders Company 1988:209.)

Choreoathetosis: 'A condition marked by choreic (involuntary, jerky and rapid) and athetoid (slow and writhing) movements.' (W.B. Saunders Company 1988:328.)

Hyperuricaemia: The term 'hyperuricaemia' is used when serum levels of monosodium urate exceed a concentration of 0,42 mmol/l (milli mols per litre) in males, and 0,36 mmol/l in females, at 37°C (Klemp 1997).

Placebo: A pharmacologically inert substance intended to act through a psychological mechanism. They have two main functions, one of which is to distinguish pharmacological effects from the effects of suggestion, and the other is to obtain an unbiased assessment of the result of experiment. (Beecher 1955.)

Tophi: 'Chalky deposits of sodium urate occurring in gout.' (W.B. Saunders Company 1988:1733.)

Uricosuric drugs: 'An agent that promotes the excretion of uric acid in the urine.' (W.B. Saunders Company 1988:1792.)

Urolithiasis: '...diseased condition associated with the presence of urinary calculi.' (W.B. Saunders Company 1988:1795.)

Xanthine oxidase: '...enzyme which catalyzes the formation of uric acid.' (Conn et al. 1987:545.)

CHAPTER ONE

INTRODUCTION

Gout is defined as a group of symptoms caused by the tissue deposition of monosodium urate monohydrate (uric acid) crystals from supersaturated extracellular fluids (Levinson and Becker 1993 2: 1773-1805). Gout is the main clinical manifestation of hyperuricaemia (Mc Gill 1997) but although hyperuricaemia is a prerequisite for the development of the disease, it is not necessary for the diagnosis of gout (Boss and Seegmiller 1979).

Gout is recognized as the most common inflammatory arthropathy in males over the age of 40 years (Cohen and Emmerson 1994) and although chronic tophaceous gout has become quite uncommon, hyperuricaemia and acute gout are still common clinical entities (Sloan 1982).

Not treated, acute gout attacks may become more frequent and last for longer periods of time (Levinson and Becker 1993 2: 1773-1805) until they merge into each other and cause increasing joint damage eventually restricting joint function. There is also a 60% chance of untreated patients developing tophi after 10 years (Nuki 1993: 983-996).

Although resolution is much faster with appropriate treatment, acute attacks of gout generally settle, even without treatment (Mc Gill 1997). Conventional allopathic treatment includes non-steroidal anti-inflammatory drugs (NSAID's) and corticosteroids to control the acute arthritis attacks while mainly allopurinol is used as long term treatment to lower uric acid levels (Mc Gill 1997). Urate lowering drugs are usually only considered after the 2nd or 3rd attack of gout and a decision to treat commits the patient to lifelong therapy (Cohen and Emmerson 1994).

In a double blind study conducted by Puterman (1994), it was found that homoeopathic *Colchicum autumnale* alleviated the associated symptoms of gout although it was not successful in reducing blood uric acid levels to normal. This study proposes that homoeopathic *simillimum* treatment will have a wider range of effectiveness in treating patients with gout. Although *simillimum* treatment has been used for over 200 years in successful treatment of various conditions, no research has been published confirming its effect on the treatment of gout.

CHAPTER TWO

REVIEW OF THE RELATED LITERATURE

2.1 INTRODUCTION

Gout is a syndrome caused by an inflammatory response to the deposition of monosodium urate crystals in the joints. The crystals are formed secondary to hyperuricaemia (although the presence of hyperuricaemia alone is not sufficient for the development of gout). (Becker 1988.)

Acute gouty arthritis is characterized by its sudden onset leading to severe pain in, swelling of and redness over the affected joint. There is first metatarsophalangeal joint involvement in about 90% of patients and initial attacks are generally monoarticular. (Mc Gill 1997)

In the 5th century BC, Hippocrates had already noted the predilection of gout in men and postmenopausal women and believed that triggering factors include excess wine, food and sex. He was also the first to describe gout of the big toe as podagra, a term that is still being used today (Levinson and Becker 1993 2: 1773-1805).

2.2 CLASSIFICATION

Although the classification of hyperuricaemia and gout are the same, the clinical presentation of these two conditions may be different.

Classification is based on uric acid handling whereby hyperuricaemia may occur as a result of either an under-excretion or an over-production of urate. Approximately 10 to 20% of patients with gout are over-producers while 80 to 90% are under-excretors of uric acid (Boss and Seegmiller 1979).

Reduced urate filtration, enhanced uric acid reabsorption or decreased urate secretion may all contribute to decreased urate clearance (Levinson and Becker 1993 2: 1773-1805).

Under-excretion and over-production are further sub divided into primary or secondary causes. In primary gout, the basic metabolic defect is unknown or, if known, the main manifestation of the defect is hyperuricaemia and gout (Scott 1980). It is believed that a reduction in the clearance of uric acid is responsible for hyperuricaemia in 90% of patients with primary gout.

Secondary gout is the term that is used when gout appears as part of another acquired disorder (Boss and Seegmiller 1979).

2.3 URIC ACID

In humans, uric acid represents the end product of purine metabolism because of an absence of the enzyme uricase that is responsible for converting uric acid into allantoin (Conn *et al.* 1987: 544-546). Purines are derived from two main sources: dietary intake and normal turnover of cells (Sloan 1982).

Uric acid is a weak acid that occurs in the blood as a urate ion. Of the extracellular uric acid, 98% occurs in the form of monosodium urate (Cohen and Emmerson 1994). About two thirds of uric acid gets excreted through the kidneys and about one-third through the intestinal tract (Wallace and Singer 1988: 195-207). Intestinal bacteria possess enzymes that degrade uric acid in the intestinal tract to carbon dioxide and ammonia (Boss and Seegmiller 1979).

Although hyperuricaemia is a risk factor in the development of gouty arthritis, gout may never develop in some hyperuricaemic people. (Cohen and Emmerson 1994.)

2.3.1 EPIDEMIOLOGY

Serum urate levels in children are lower than levels in adults but during male puberty they rise to adult levels. The lower levels found in premenopausal women is thought to be due to the effect of estrogenic compounds on renal urate clearance. After menopause, serum urate levels in women rise approaching that of men of corresponding age, thus also causing an increase in the incidence of gout. (Becker 1988.)

2.3.2 AETIOLOGY AND PATHOGENESIS OF HYPERURICAEMIA

a) Over-production of uric acid

Overproduction may be due to exogenous factors such as dietary intake of purines (e.g. red meat), or endogenous factors (Cohen and Emmerson 1994) such as increased nucleotide catabolism (e.g. myeloproliferative disorders) (Carsons 1997).

i) Enzyme defects (Primary)

Basic defects in the mechanisms regulating purine nucleotide synthesis can

cause an overproduction of purines. These defects are associated with enzymatic defects. A partial deficiency of HGPRT (hypoxanthine-guanine phosphoribosyltransferase) and milder forms of superactivity of PRPP (5-phosphoribosyl 1-pyrophosphate synthetase) can cause early adult onset of gout and a high incidence of uric acid urinary tract stones. In contrast, a group of symptoms called Lesch-Nyhan syndrome is caused when the HGPRT deficiency is severe. These symptoms include spasticity, choreoathetosis, mental retardation and compulsive self-mutilation. (Wallace and Singer 1988: 195-207.)

ii) Increased cell turnover (Secondary)

Overproduction of uric acid occurs in a variety of acquired and genetic disorders that are characterized by excessive cell and, therefore, nucleic acid turnover. These disorders include myeloproliferative and lymphoproliferative diseases, haemolytic anaemias and psoriasis. (Carsons 1997.)

iii) Excessive purine ingestion (Secondary)

b) Under-excretion of uric acid

i) Idiopathic (Primary)

Caused by an unknown metabolic disturbance.

ii) Drug-induced hyperuricaemia (Secondary)

Diuretics and aspirin are the drugs most often associated with hyperuricaemia. Although the precise mechanism involved is not clear, it is believed that they may increase reabsorption of uric acid in the proximal tubule. Other hypotheses have included a decrease in tubular secretion or an increase in postsecretory reabsorption of uric acid. The only diuretic that has not been implicated as a cause of hyperuricaemia is spiro lactone. (Boss and Seegmiller 1979.)

Low doses of aspirin inhibit tubular secretion of uric acid, while high doses inhibit the reabsorption of uric acid.

It is believed that drugs that cause a rapid change in the serum uric acid level may trigger attacks by interrupting the protein coating on the urate crystals that prevents the reaction of the inflammatory system (Mc Gill 1997).

iii) Increased level of organic acids (Secondary)

Ethyl alcohol used in excess is known to cause hyperuricaemia by inducing lactic acidosis. Lactic acid competes with uric acid for renal secretory sites, thus inhibiting tubular secretion of urate (Boss and Seegmiller 1979; Simkin 1979).

Many alcoholic beverages such as beer and wine also have a high purine content (Sloan 1982). Alcohol also contributes to the degradation of adenine nucleotides thus increasing urate production (Cohen and Emmerson 1994).

Hyperuricaemia may also occur in uncontrolled diabetes, in starvation and after exercise due to keto acids and lactic acids inhibiting tubular secretion of uric acid (Boss and Seegmiller 1979).

iv) Heavy metals (Secondary)

The presence of heavy metals interfere with the ability of the proximal tubule to secrete uric acid thus causing hyperuricaemia. The metal most often associated with hyperuricaemia is lead (saturnine gout). A high incidence of gout has been found in the lead-intoxicated users of unbonded whiskey in the southeastern United States. (Loghman-Adham 1997.)

v) Miscellaneous

Obesity, hyperlipidaemia and impaired glucose tolerance are commonly associated with gout. Obesity may be the common linking factor as men with gout are generally 15 to 20% overweight. (Gelber et al. 1997.)

Hypertension may be associated with hyperuricaemia in three ways: i)

Hypertension reduces renal excretion of urate; ii) renal damage from interstitial micro tophi may lead to secondary renal hypertension and iii) excessive alcohol consumption may cause both hyperuricaemia and hypertension (Cohen and Emmerson 1994).

2.4 GOUT

2.4.1 EPIDEMIOLOGY

Although determining the precise incidence and prevalence of gout is difficult due to the relapsing nature of the disease, it is still recognized as being the most common inflammatory arthropathy in males over the age of 40. (Cohen and Emmerson 1994.)

Gout is uncommon before the age of 30 (Levinson and Becker 1993 2: 1773-1805) and the peak incidence of primary gout occurs in the 5th decade in males and postmenopausally in females (Grahame and Scott 1970). These differences reflect the age-related patterns of serum urate levels. Although studies have shown that racial differences do exist in the prevalence of gout and hyperuricaemia, it is difficult to make estimates due to the influence of genetic and environmental factors (especially with regard to diet) (Cohen and Emmerson 1994).

2.4.2 PATHOGENESIS

When extracellular fluid becomes supersaturated with uric acid, crystals start forming in joints and other connective tissue sites. Initially the deposition of crystals is asymptomatic but direct trauma or metabolic changes may loosen the crystals thus triggering an inflammatory response (Star and Hochberg 1993). Neutrophils attempting to phagocytise crystals may lyse, releasing lysosomal enzymes increasing the inflammatory response. Mediators cause vasodilation and increased vessel permeability increasing neutrophilic action. The irregular surfaces of the crystals also play an important role in increasing the inflammatory response (Sloan 1982).

The fact that lower temperature reduces the solubility of the crystals, has been used to explain the predilection of gout for the peripheral joints. (Cohen and Emmerson 1994; Sloan 1982.)

When the urate concentration in the extracellular fluid decreases, the urate crystals and tophi may be resorbed completely. The tissues return to normal except for some degree of fibrosis (Cohen and Emmerson 1994). Recurrent inflammatory responses will eventually lead to joint and bone damage (Mc Gill 1997).

2.4.3 CLINICAL FEATURES

Gout tends to occur in three general stages:

- a) A long period of hyperuricaemia may exist, which is asymptomatic. Many people have lifelong hyperuricaemia without gout ever developing.
- b) Frequent, recurrent attacks of acute gouty arthritis is characterized by its abrupt onset (usually waking the patient), swelling, redness, heat and extreme pain. Very acute attacks may be associated with fever, leucocytosis and a raised erythrocyte sedimentation rate. An acute attack may last from a few days to a few weeks in untreated patients. Classically, acute attacks occur in the peripheral joints with about 90% affecting the first metatarsophalangeal joint. Other joints that may be affected are the ankle, heel, toe, wrist, fingers and elbows. Usually only one joint is affected but polyarticular attacks do occur (more often in women). During resolution, there may be desquamation and pruritis of the skin over the affected joint and once the attack has subsided, the patient enters another period of asymptomatic gout termed 'intercritical' gout.
- c) A final stage of chronic tophaceous gout tends to occur when gout has been left untreated. As the disease progresses, the attacks become polyarticular, more frequent and more prolonged with an incomplete resolution between attacks. Initially the affected joints recover completely but repeated attacks may cause the formation of bony erosions, deposition periarticular and subcutaneous urate deposits (tophi), and degenerative changes thus affecting joint mobility. (Becker 1988.)

Tophi usually occur in the digits of the hands and feet, the olecranon bursa and helix or antihelix of the ear as firm nodular swellings. They may be associated with local inflammation causing the overlying skin to be erythematous. When they are close to the skin surface, they may appear yellow in colour and in ulcerated tophi, white chalky material may exude. Most of the disability that is seen in gout is due to the presence of these tophi. (Scott 1980.)

Hyperuricaemia may affect the kidney through 1) deposition of urate crystals in the renal interstitium referred to as urate nephropathy; 2) deposition of uric acid crystals in the collecting tubules, referred to as uric acid nephropathy and 3) uric acid urolithiasis. The distinction

between the first two conditions is often unclear and the term 'gouty kidney' is used for both. Although urate nephropathy is not uncommon in patients with gout, both uric acid nephropathy and urolithiasis are more common in patients with excessive uric acid production and excretion (Levinson and Becker 1993 2: 1773-1805). When untreated, the resulting obstruction and infection from recurrent urolithiasis can cause significant irreversible renal damage (Sloan 1982). Renal insufficiency usually does not occur as a result of gout but its presence may complicate the treatment of gout (Mc Gill 1997).

2.4.4 DIAGNOSIS

The standard procedure for the diagnosis of gout is the identification of negative birefringent crystals in synovial fluid or tophi using compensated polarized light microscopy (Becker 1988). This method is not only costly and invasive (thus not being suitable for the study of large groups of patients), but crystals are often only found 15% of the time in acute gout (Wallace et al. 1977).

Using the presence of hyperuricaemia as sole criteria also causes problems as it has been found that serum urate concentrations may be normal during an acute attack of gout (Schlesinger et al. 1997). In 1977, the American Rheumatism Association (ARA) developed standard criteria for the classification of gout in order to achieve a uniform system for reporting and comparing data. Current epidemiological studies define gout using the ARA criteria, where the presence of 6 of the 11 criteria have an overall sensitivity of 84,8% (Wallace et al. 1977).

In a study done by Klemp et al. (1997), it was suggested that further studies also use the ARA criteria for the classification of gout, that serum uric acid be analyzed using the uricase method and that hyperuricaemia be defined as a serum uric acid level of >0,42 mmol/litre in men and >0,36 mmol/litre in women.

Acute gouty arthritis can be easily confused with conditions such as traumatic arthritis, cellulitis (not limited to joints) and pseudo-gout. Of these conditions pseudo-gout is the most commonly confused with gout but unlike with gout, there is a normal serum urate level, the most common joint affected is the knee, and the crystals that are found in the joints are composed of calcium

pyrophosphate. Chronic tophaceous gout may be confused with rheumatoid arthritis, especially when tophi are confused with rheumatoid nodules. (Cohen and Emmerson 1994; Levinson and Becker 1993 2: 1773-1805.)

Another possible method of diagnosis is the use of the Acupulse Homeostat machine which is an electrodermal screening device (an ohm-meter designed to deliver approximately 10-12 microamperes of direct electrical current at 1-1,25 volts). It measures slight electrical changes in points on the skin, enabling it to evaluate the status of certain organs of the body as well as the reaction of the body to medication. This method of measurement is known as Electrodermal Screen Testing (EDST). The readings from a healthy person would be 50 units, whereas a deviation from 50 units is a good indication of disease. (Grove, 1999)

2.5 ALLOPATHIC MANAGEMENT

In cases where the blood uric acid level falls under 50mmol/l, lifestyle changes may be effective treatment. Limiting uric acid retaining medication, losing weight and lowering alcohol and purine-rich food consumption can be very effective but few patients are able to achieve and maintain this type of lifestyle change. (Star and Hochberg 1993.) Allopathic management has two objectives: 1) Control of acute attacks of gouty arthritis and 2) control of hyperuricaemia to prevent subsequent attacks and long-term complications. (Boss and Seegmiller 1979.)

2.5.1 ACUTE GOUT

Generally, non-steroidal anti-inflammatory drugs (NSAID's) are used where patients have no contra-indications to it. All NSAID's are effective but most cause gastrointestinal disturbances and should be prescribed with food or antacids (Landry and Schilero 1986). A definite contra-indication to the use of NSAID's is the presence of active peptic ulcer disease and gastrointestinal bleeding. The only NSAID that is to be avoided is aspirin because, although high doses of aspirin increase uric acid clearance, low doses interfere with renal handling of uric acid. (Mc Gill 1997.)

In patients where NSAID's are contra-indicated, corticosteroids are often used. Corticosteroids have a beneficial effect on acute gouty arthritis by causing vasoconstriction, decreasing neutrophil accumulation at the site of inflammation and suppressing the action of cells involved in the inflammatory process. They may be given intra-articularly, when only one or two joints are

affected or orally. In both cases, they provide pain relief and a decrease in inflammation within a few hours. Adverse effects are usually associated with long term use and may include osteoporosis, myopathy, psychiatric complications and a predisposition to infections. (Groff et al. 1990.)

Colchicine (an alkaloid found in extracts of the plant *Colchicum autumnale*) was once the drug of choice for acute gout but, because of potential toxicity, is now only used in low doses (King and Nicholas 1997). Colchicine is an antimitotic agent, decreasing leucocyte migration and phagocytosis (Star and Hochberg 1993). Unfortunately most patients suffer from adverse effects such as diarrhoea, nausea and vomiting. Although traditional high dose colchicine therapy is poorly tolerated and has many adverse effects, low dose colchicine is still used especially during an acute attack as it inhibits the neutrophil function. (Mc Gill 1997.)

2.5.2 PROPHYLAXIS

Patients who are started on chronic prophylactic treatment often suffer from an increase in acute attacks. This is related to the mobilization of uric acid stores and it is for this reason that low dose colchicine is often given in conjunction. (Scott 1980.) Low dose colchicine may be used as prophylaxis of recurrent attacks of gout.

Treatment of hyperuricaemia is usually only started after recurrent attacks of acute gout (Mc Gill 1997). Control of hyperuricaemia is important in preventing gout and is achieved by the use of antihyperuricaemic therapy. The treatment of hyperuricaemia is divided into two categories: xanthine oxidase inhibitors and uricosuric drugs. (Star and Hochberg 1993).

Allopurinol is the most popular drug for prophylaxis as it works by inhibiting xanthine oxidase, the enzyme responsible for urate synthesis (Landry and Schilero 1986). It has been found to lower both serum urate and urinary urate levels. The most common side effects of Allopurinol include hypersensitivity reactions, skin rashes and gastrointestinal distress. When Allopurinol is discontinued, blood uric acid levels rise rapidly to pre-treatment levels but gouty arthritis only recurs in a few cases. This may be due to the fact that the total body content of urate is lowered throughout the treatment period and time is required for the redevelopment of gout. (Loebl and Scott 1974.)

Uricosuric drugs such as probenecid and sulfinpyrazone increase uric acid excretion by inhibiting reabsorption of uric acid in the kidney. (Star and Hochberg 1993.) This leads to a reduction in serum urate concentration and promotes reabsorption of tophi (Sloan 1982). Uricosuric drugs may cause urolithiasis and should be used with an increased fluid intake. Alkalinization drugs may be used but is not practical over a long-term period. Uricosuric drugs are contra-indicated in patients who are over-producers of uric acid and in patients with a history of renal stones (King and Nicholas 1997).

2.5.3 SURGERY

Surgical intervention may be indicated where the treatment of the disease has been neglected and tophaceous deposits interfere with movement and cause pain. (Landry and Schilero 1986.)

2.6 HOMOEOPATHIC MANAGEMENT

'Homoeopathy' comes from the words '*Homoeo*', meaning 'like' and '*Pathos*', meaning 'suffering'. It is a therapeutic method which applies the law of similars (*similia similibus curentur*) and which uses medicinal substances in weak or infinitesimal doses. (Lockie and Geddes 1995: 14.) This means that a substance that produces certain symptoms in a healthy person will cure the same symptoms when given to a sick person.

The underlying concept of homoeopathy is that, in all conditions of ill health, the human body is fully capable of healing itself by means of the vital force. (Jouanny 1991: 11.)

The homoeopath can treat gout through clinical treatment or simillimum treatment.

2.6.1 CLINICAL TREATMENT

The prescription is based on the symptoms presented by the patient with regards to gout only. (Lockie and Geddes 1995: 14.)

2.6.2 SIMILLIMUM TREATMENT

The prescription is based on a full evaluation of the patient's physical, emotional and mental characteristics. This is especially effective when the disease is chronic. (Lockie and Geddes 1995: 14.)

2.7 SUMMARY

Although allopathic drug treatment may be effective especially in preventing complications, the decision to treat commits the patient to life-long treatment. (Sloan 1982) This treatment often causes the patient severe discomfort in the form of side effects and increasing medical costs make chronic medication inaccessible to many patients.

Homoeopathic medicines have been used effectively for many years to treat gout but very little research has been done in this field.

CHAPTER THREE

MATERIALS AND METHODS

The purpose of this double-blind study was to compare a treatment group with a placebo group in order to assess the response of patients suffering from gout to homoeopathic simillimum treatment.

3.1 STUDY DESIGN AND PROTOCOL

A total of 30 patients were selected. They were randomly divided into two groups in such a way that each patient had an equal chance of being selected for either group. Fifteen pieces of paper labeled 'treatment' and fifteen pieces of paper labeled 'placebo' were placed into a box. An independent person drew out one piece of paper at a time and allocated it to a list of numbers from one to thirty. The first patient received the first treatment etc. The independent person kept the list until the study was completed.

Prospective patients were screened according to the selection criteria as discussed in section 3.2.

Once included in the study, patients were required to fill in an 'Informed Consent' form as well as the questionnaire (Appendix B).

A complete homoeopathic and medical case history was taken, followed by a physical examination. During the physical examination, the uric acid point was measured using the Acupulse Homeostat machine.

Each case was repertorized using Synthesis (7th edition) and Radar, and prescriptions were confirmed by a qualified homoeopath at the clinic.

Medication was dispensed by an independent person and the patient was sent for a blood test to a professional pathology laboratory.

Two follow up consultations were done two weeks apart during which changes were recorded and readings were taken using the Acupulse Homeostat machine.

The patient was also required to fill in the questionnaire at each consultation and again undergo blood tests.

Follow up prescriptions were based on any changes that had taken place and were supervised by a qualified homoeopath.

3.2 SUBJECTS

Thirty patients from the greater Durban area were screened by the researcher according to the inclusion and exclusion criteria:

3.2.1 INCLUSION CRITERIA

- a) Patients had to present with six of the seven criteria taken from the American Rheumatism Association's criteria for acute arthritis of primary gout (appendix A).
- b) Patients from all race groups were included in the study.
- c) Patients from both sexes were included in the study.

3.2.2 EXCLUSION CRITERIA

- a) Any patient who had received medication for gout or any other medication that would effect uric acid metabolism in the month prior commencement of treatment.
- b) Any patient with renal or hepatic disease or any other disease causing secondary gout.

3.3 ETHICS

The nature of the study was explained to each patient at the outset by the researcher. Each patient was asked to read the information sheet (appendix C) and complete the informed consent form (appendix D).

3.4 TREATMENT

3.4.1 HOMOEOPATHIC SIMILLIMUM TREATMENT

The medicine used by the treatment group, was obtained from the dispensary at the Technikon Natal Homoeopathic Day Clinic where it was prepared under strict control in accordance with the Homoeopathic Pharmacopoeia.

The medication was dispensed, by an independent person, in the form of powders and was

taken orally.

There was no standardization of remedy, potency or dosage, as it varied for each patient

according to simillimum. The following medicines were prescribed:

Calcarea carbonica 30CH (1 patient)	Natrum phosphoricum 200CH (1 patient)
Calcarea carbonica 200CH (2 patients)	Natrum sulphuricum 200CH (2 patients)
Carcinosinum 200CH (1 patient)	Natrum sulphuricum 1M (1 patient)
Crotalus horridus 200CH (1 patient)	Nitricum acidum 200CH (1 patient)
Ferrum phosphoricum 200CH (1 patient)	Rhus toxicodendron 30CH (2 patient)
Lac caninum 30CH (1 patient)	Rhus toxicodendron 200CH (1 patient)
Ledum 12CH (1 patient)	Sepia 200CH (1 patient)
Ledum 30CH (1 patient)	Silicea 200CH (1 patient)
Lycopodium 15CH (1 patient)	Staphisagria 30CH (1 patient)
Lycopodium 30CH (2 patients)	Staphisagria 200CH (1 patient)
Lycopodium 200CH (2 patients)	Sulphur 30CH (1 patient)
Natrum carbonicum 200CH (1 patient)	Sulphur 200CH (1 patient)
Natrum muriaticum 200CH (1 patient)	

3.4.2 PLACEBO TREATMENT

The placebo group was used as a control group. Powders given to this group were unmedicated, given orally and were dispensed in the same manner as the homoeopathic treatment.

3.5 MEASUREMENTS AND OBSERVATIONS

Data collected for the study was obtained using :

3.5.1 The 'Illness Intrusiveness Ratings Scale' questionnaire (Lorig *et al.* 1996: 60).

3.5.2 The Acupulse Homeostat machine

3.5.3 Blood uric acid levels

3.5.1 ILLNESS INTRUSIVENESS RATINGS SCALE QUESTIONNAIRE

This questionnaire was used in order to get an idea of how gout affected all aspects of the patients' life and whether that effect was decreased after the use of homoeopathic treatment.

The questions covered the following main aspects:

Physical well-being and diet

Work and finances

Marital, sexual and family relations

Recreation and social relations

Other aspects of life

The questionnaire was completed during the initial consultation as well as the two follow up consultations.

3.5.2 ACUPULSE HOMEOSTAT MACHINE

Although many practitioners use the Acupulse Homeostat machine, no scientific research has been done in this area.

In this study, the Acupulse Homeostat machine was used to obtain a reading at the uric acid point and then comparing the result with those of the blood test.

Reading is done by placing one electrode in the patients' hand and the end of the other electrode on the uric acid point. The point that measures uric acid abnormality is believed to be situated on the third toe of the right foot, medially to the toenail.

This method of measurement is known as Electrodermal Screen Testing (EDST).

According to Grove (1999), developer of the Acupulse Homeostat machine, it can also establish whether a remedy will have an effect on the health of a patient before the patient actually takes the medication. This is done by first taking a normal measurement. The measurement is repeated but with the medication placed on a copper plate on the machine. If the reading improves, it is believed that the patient will benefit by taking the remedy. These results were recorded but did not influence the decision of the simillimum remedy.

Normal measurements were taken at the initial consultation as well as during the two follow up consultations whereas measurements testing the potential efficacy of the remedy were only taken during the initial consultation.

3.5.3 BLOOD URIC ACID LEVELS

All patients were sent for blood tests after the initial as well as follow up consultations. These

tests were done by a professional pathology laboratory to determine the blood uric acid levels. Blood samples were analyzed using the uricase conversion method. A level above 0.42mmol/l in males was considered high and a level above 0.36mmol/l in females was considered high.

3.6 STATISTICAL PROCEDURES

Data obtained from the Illness Intrusiveness Ratings Scale questionnaire, blood tests and the Acupulse Homeostat machine, were used for statistical analysis.

Because of the small sample size ($n_1 = 15$, $n_2 = 15$), and the fact that the 12 questions in the questionnaire were measured in ordinal scales, non-parametric methods were used to analyze the variables.

Since the Electrodermal Screen Testing (EDST) and the uric acid test (UAT) are continuous variables, parametric tests were used for the analysis regardless of the small sample size per group.

Data entry and analysis was performed using the statistical computer package SPSS.

Group 1 constituted the treatment group (homoeopathic simillimum treatment).

Group 2 constituted the control group (placebo treatment)

3.6.1 PROCEDURE 1: COMPARISON BETWEEN GROUPS 1 AND 2

The Mann-Whitney unpaired two-tailed test was used to compare Groups 1 and 2 with respect to the 12 variables in the questionnaire.

Comparison between group 1 and group 2 was also made with regards to EDST and UAT using the two-sample unpaired t-test.

The purpose of this test was to determine whether there was any significant difference between the two groups. The null-hypothesis states that there is no significant difference between Group 1 and Group 2 with respect to the variables in charge, at the $\alpha = 0.05$ level of significance.

The alternative hypothesis states that there is a significant difference.

Decision rule:

The null hypothesis is rejected at the α level of significance if $p \leq \alpha/2$ (p is the observed

significant level of the test).

Reject H_0 if $p \leq \alpha/2 = 0.05/2 = 0.025$

Accept H_0 if $p > \alpha/2 = 0.05/2 = 0.025$

3.6.2 PROCEDURE 2: COMPARISON BETWEEN RELATED SAMPLES WITHIN GROUP 1

The Wilcoxon's signed ranks test was used to compare results from group 1 with respect to the 12 questions in the questionnaire.

Comparison was also made between related samples within group 1 with respect to EDST and UAT using the two sample paired t-test.

In each test, the null-hypothesis states that there is no significant improvement between the 2 related samples being compared, at the α level of significance.

The alternative hypothesis states that there is significant improvement.

Decision rule:

The null hypothesis is rejected at the α level of significance if $p \leq \alpha/2$ (p is the observed significant level of the test).

Reject H_0 if $p \leq \alpha/2 = 0.05/2 = 0.025$

Accept H_0 if $p > \alpha/2 = 0.05/2 = 0.025$

3.6.3 PROCEDURE 3: COMPARISON BETWEEN RELATED SAMPLES WITHIN GROUP 2

The Wilcoxon's signed ranks test was used to compare results from group 2 with respect to the 12 questions in the questionnaire.

Comparison was also made between related samples within group 2 with respect to EDST and UAT using the two sample paired t-test.

In each test, the null-hypothesis states that there is no significant improvement between the 2 related samples being compared, at the α level of significance.

The alternative hypothesis states that there is significant improvement.

Decision rule:

The null hypothesis is rejected at the α level of significance if $p \leq \alpha/2$ (p is the observed significant level of the test).

Reject H_0 if $p \leq \alpha/2 = 0.05/2 = 0.025$

Accept H_0 if $p > \alpha/2 = 0.05/2 = 0.025$

3.6.4 PROCEDURE 4: COMPARISON BETWEEN EDST AND UAT RESULTS

The two-sample t-test (both hypothesis testing and construction of confidence intervals) was used to compare EDST and UAT results.

3.6.5 PROCEDURE 5: AVERAGE AND STANDARD DEVIATIONS FOR CONTINUOUS VARIABLES

Averages and standard deviations were computed for continuous variables only, and were used for power analysis. Power analysis was done for the variables EDST and UAT.

3.6.6 PROCEDURE 6: COMPARISON USING BARCHARTS

Visual summaries of analytical findings were given by the using barcharts to compare groups 1 and 2 with respect to EDST, UAT and the 12 questions from the questionnaire.

3.6.7 PROCEDURE 7: POWER ANALYSIS FOR CONTINUOUS VARIABLES ONLY

Power analysis was done for the EDST and UAT (the continuous variables mentioned above).

CHAPTER FOUR

RESULTS

4.1 QUESTIONNAIRE

Table 4.1.1: Comparing the treatment and placebo group p-values calculated from the questionnaire (data obtained from questionnaire with 12 questions)

(Mann-Whitney Unpaired Test)

	Consultation 1	Consultation 2	Consultation 3
Questions	P-value	P-value	P-value
1. Health	0.799	0.570	0.585
2. Diet	0.597	0.556	0.437
3. Work	0.801	0.413	0.815
4. Active recreation	0.347	0.274	0.705
5. Financial situation	0.734	0.881	0.898
6. Relationship with partner	0.574	0.178	0.793
7. Sex life	0.729	0.110	0.568
8. Family relations	0.930	0.345	0.706
9. Other social relations	0.474	0.373	0.948
10. Self expression / improvement	0.413	0.849	0.783
11. Religious expression	0.847	0.324	0.925
12. Community & civic involvement	0.748	0.847	0.512

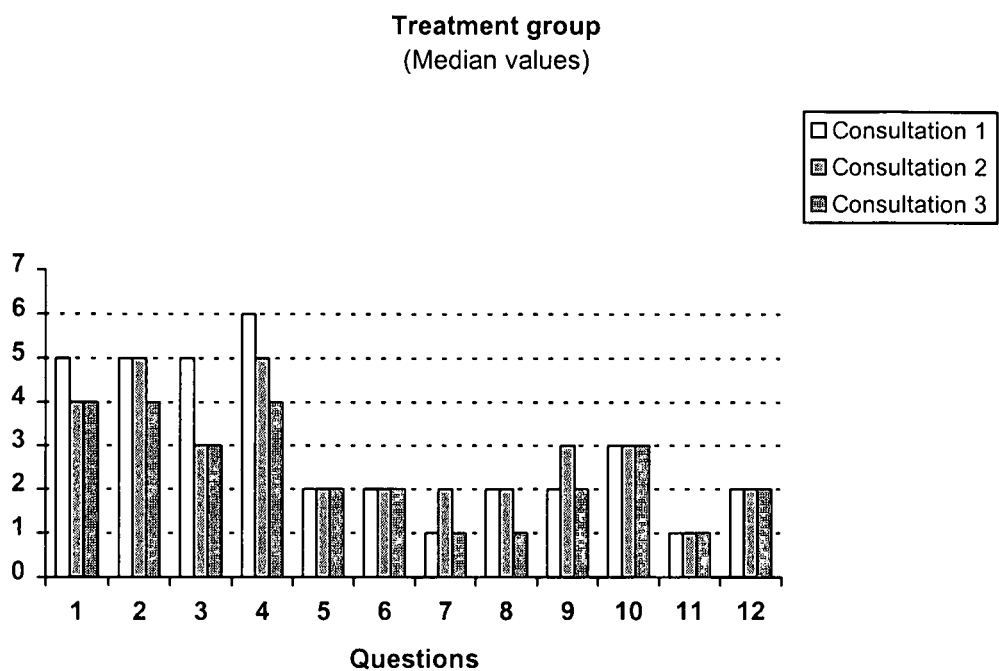
The table demonstrates that there is no significant difference between the groups, hence H_0 is not rejected.

Table 4.1.2: Comparison of the p-values between consultation 1, 2 and 3 within the treatment group (data obtained from questionnaire with 12 questions)
(Wilcoxon's Signed Rank Test)

Questions	Consult. 1 & 2 P-value	Consult. 2 & 3 P-value	Consult. 1 & 3 P-value
1. Health	0.107	0.679	0.033
2. Diet	0.959	0.093	0.098
3. Work	0.140	0.783	0.105
4. Active recreation	0.004	0.779	0.017
5. Financial situation	0.314	0.680	0.667
6. Relationship with partner	0.904	0.083	0.379
7. Sex life	0.257	0.114	0.380
8. Family relations	0.427	0.131	0.660
9. Other social relations	0.642	0.163	0.288
10. Self expression / improvement	0.873	0.248	0.368
11. Religious expression	0.606	0.414	0.931
12. Community & civic involvement	0.666	0.287	0.222

From the above table it can be seen that H_0 is generally not rejected except with regard to question four, showing that there was significant improvement with regard to *active recreation* in the treatment group.

Graph 4.1.1: Comparison between consultation 1, 2 and 3 within the treatment group
using median values



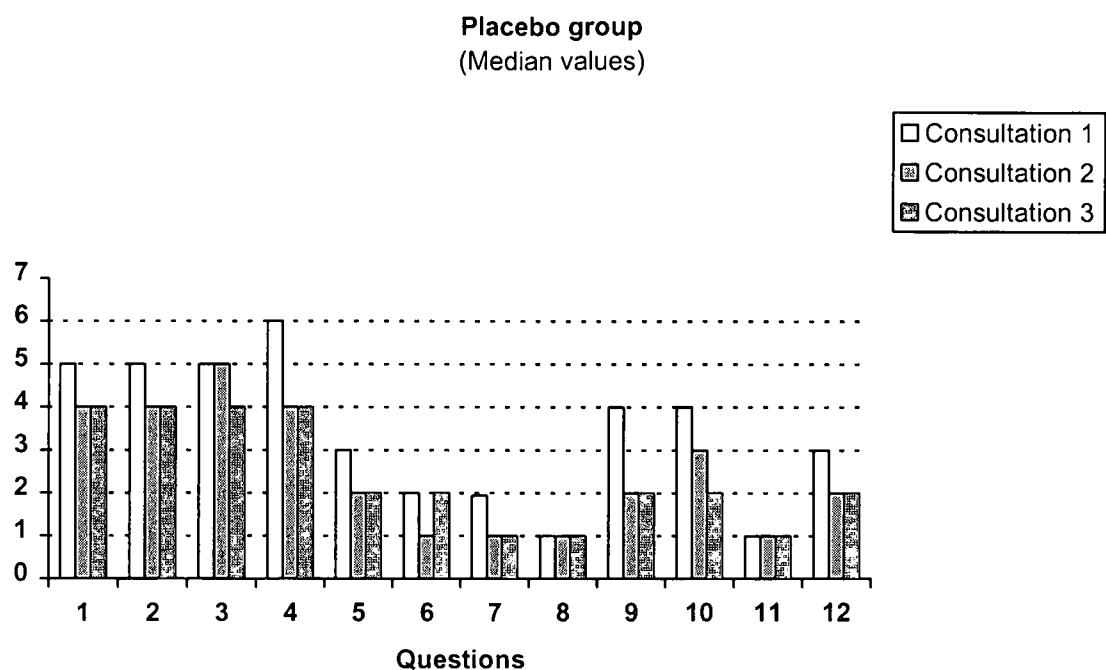
The graph shows that there was an improvement with regard to *health, diet, work* and *active recreation* (questions 1, 2, 3 and 4). *Active recreation* (question 4) shows significant improvement.

Table 4.1.3: Comparison of the p-values between consultation 1, 2 and 3 within the placebo group (data obtained from questionnaire with 12 questions)
(Wilcoxon's Signed Rank Test)

Questions	Consult. 1 & 2 P-value	Consult. 2 & 3 P-value	Consult. 1 & 3 P-value
1. Health	0.673	0.890	0.521
2. Diet	0.233	0.763	0.319
3. Work	0.865	0.132	0.330
4. Active recreation	0.051	0.595	0.054
5. Financial situation	0.350	0.414	0.196
6. Relationship with partner	0.319	0.157	0.871
7. Sex life	0.301	0.705	0.522
8. Family relations	0.206	0.655	0.172
9. Other social relations	0.147	0.655	0.209
10. Self expression / improvement	0.151	1.00	0.101
11. Religious expression	0.461	0.059	0.916
12. Community & civic involvement	0.396	0.480	0.205

The table demonstrates that there is no significant difference within the placebo group, hence H_0 is not rejected.

Graph 4.1.2: Comparison between consultation 1, 2 and 3 within the placebo group
using median values



This graph shows that there was an improvement with regard to nine of the twelve variables.

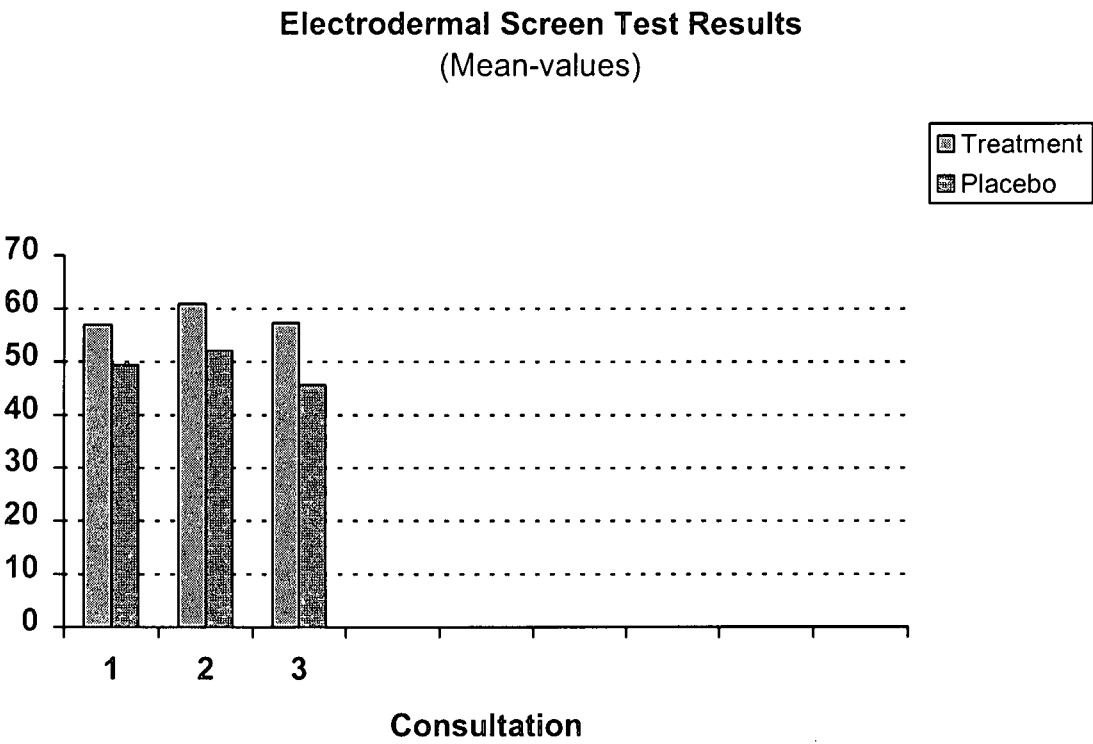
4.2 ELECTRODERMAL SCREEN TESTS

Table 4.2.1: Comparing the treatment and placebo group p-values with regards to Electrodermal Screen Test
(Two-Sample Unpaired T-Test)

	P-Values
Consultation 1	0.256
Consultation 2	0.190
Consultation 3	0.079

The table demonstrates that there is no significant difference between the groups, hence H_0 is not rejected.

Graph 4.2.1: Comparison between the treatment and the placebo group using mean values



The graph shows a similar trend in both groups with a slight aggravation at the second consultation.

Table 4.2.2: Comparison of the p-values between consultation 1, 2 and 3 within the treatment group and placebo group respectively (p-values calculated from the Electrodermal Screen Test results)

(Two-Sample Paired T-Test)

	Treatment group	Placebo group
Consultation 1 vs consultation 2	0.495	0.407
Consultation 2 vs consultation 3	0.372	0.083
Consultation 1 vs consultation 3	0.944	0.151

The table demonstrates that there is no significant difference, hence H_0 is not rejected.

4.3 URIC ACID TESTS

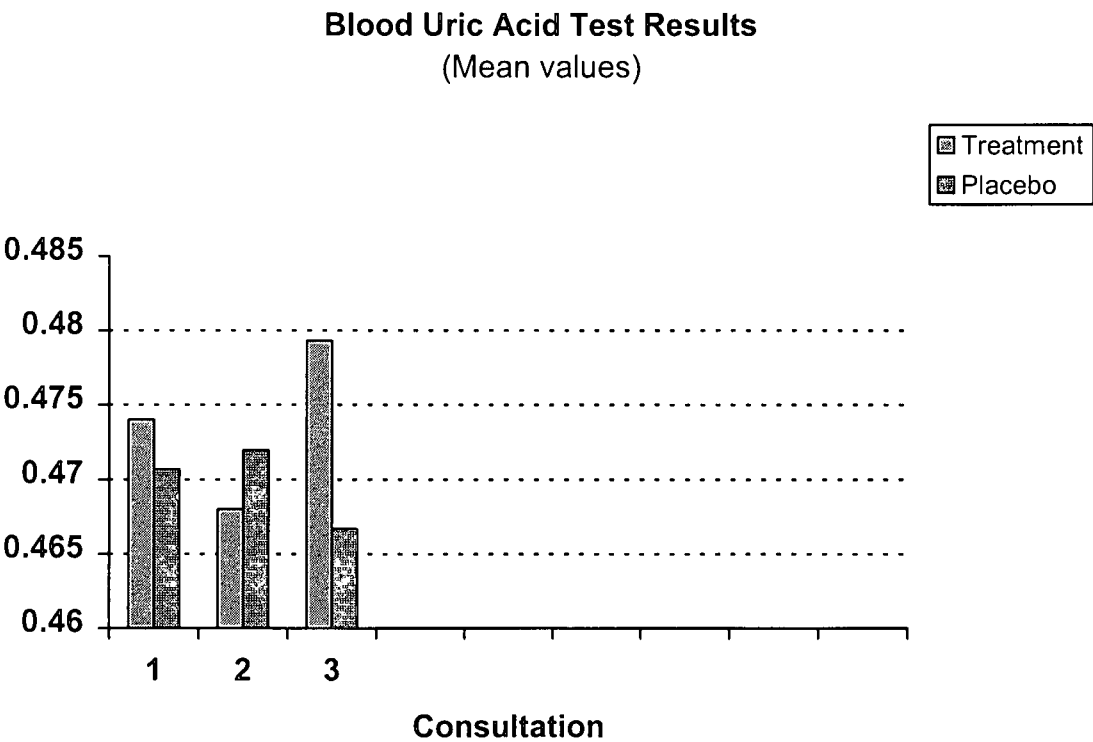
Table 4.3.1: Comparing the treatment and placebo group p-values with regards to Uric Acid Test

(Two-Sample Unpaired T-Test)

	P-Values
Consultation 1	0.954
Consultation 2	0.945
Consultation 3	0.812

The table demonstrates that there is no significant difference between the groups, hence H_0 is not rejected.

Graph 4.3.1: Comparison between the treatment and the placebo group using mean values



The graph shows that blood uric acid levels within the treatment group were lower at the second consultation but then increased sharply at the third consultation. The placebo group showed an initial increase in blood uric acid levels at the second consultation and a decrease at the third consultation.

Table 4.3.2: Comparison of the p-values between consultation 1, 2 and 3 within the treatment group and placebo group respectively (p-values calculated from the Uric Acid Test results)

(Two-Sample Paired T-Test)

	Treatment group	Placebo group
Consultation 1 vs consultation 2	0.775	0.933
Consultation 2 vs consultation 3	0.267	0.595
Consultation 1 vs consultation 3	0.804	0.698

The table demonstrates that there is no significant difference, hence H_0 is not rejected.

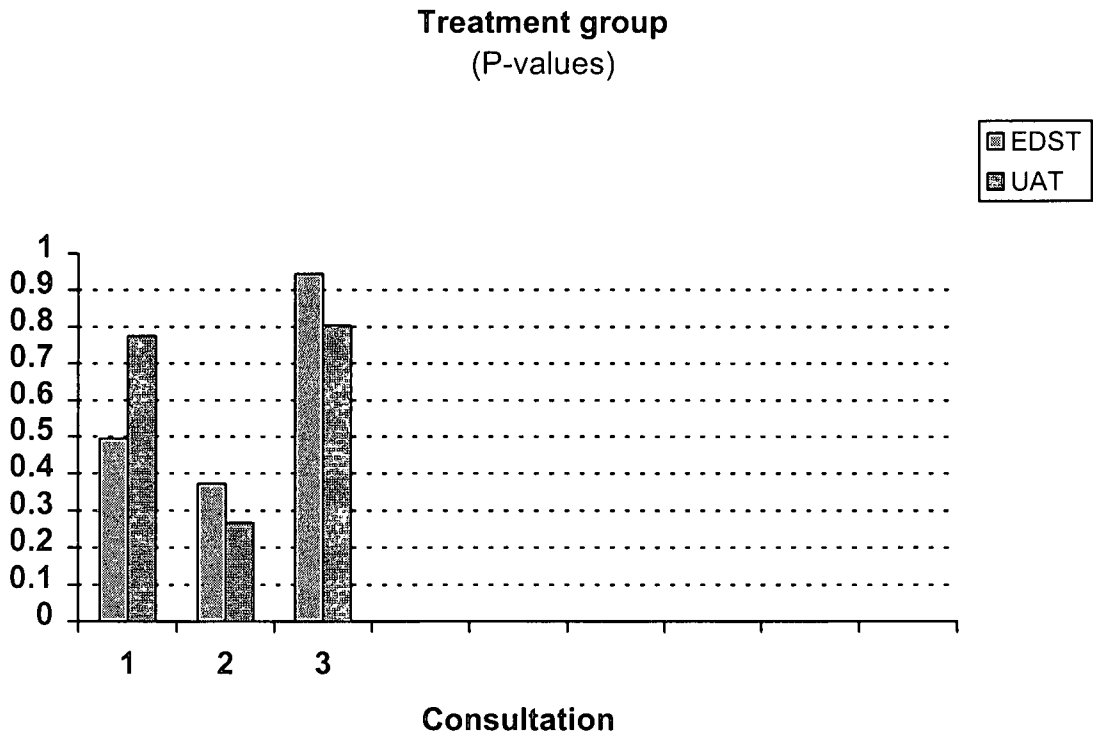
4.4 COMPARISON BETWEEN EDST AND UAT RESULTS

Table 4.4.1: Using the p-values from the above two tables to compare Electrodermal Screen Test and Uric Acid Test within the treatment group

	EDST	UAT
Consultation 1 vs consultation 2	0.495	0.775
Consultation 2 vs consultation 3	0.372	0.267
Consultation 1 vs consultation 3	0.944	0.804

The table demonstrates that there is no significant difference within the treatment group, hence H_0 is not rejected.

Graph 4.4.1: Comparison between EDST and Uric Acid Test results within the treatment group using p-values



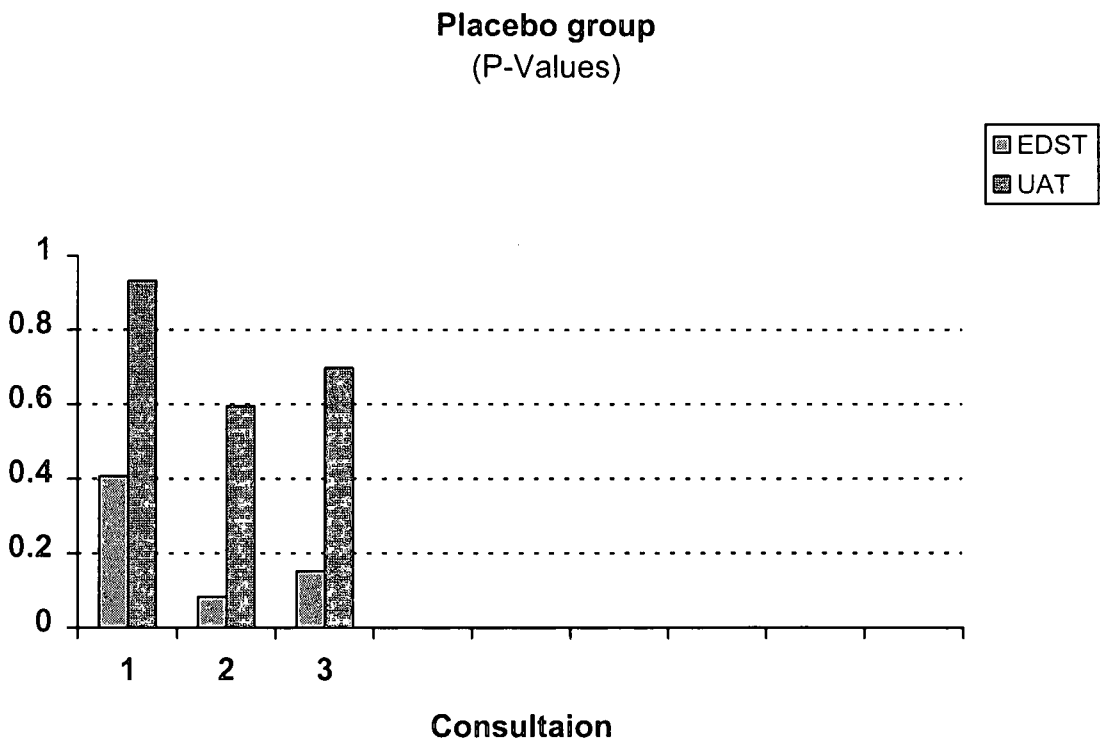
Although the graph shows a similar trend between the EDST and UAT results, there is no correlation between values measured.

Table 4.4.2: Using the p-values from the above two tables to compare Electrodermal Screen Test and Uric Acid Test within the placebo group

	EDST	UAT
Consultation 1 vs consultation 2	0.407	0.933
Consultation 2 vs consultation 3	0.083	0.595
Consultation 1 vs consultation 3	0.151	0.698

The table demonstrates that there is no significant difference within the placebo group, hence H_0 is not rejected.

Graph 4.4.2: Comparison between EDST and Uric Acid Test results within the placebo group using p-values



Although the graph shows a similar trend between the EDST and UAT results, there is no correlation between values measured.

4.5 POWER ANALYSIS

Table 4.5.1: Power analysis for Electrodermal Screen Test and Uric Acid Test

	EDST	UAT
Consultation 1	0.0563	0.0968
Consultation 2	0.0570	0.1139
Consultation 3	0.0598	0.5096

The table shows that power analysis results were low.

CHAPTER FIVE

DISCUSSION

From the results obtained, it is evident that there was very little significant difference between the homoeopathic simillimum treatment and the placebo treatment.

5.1 QUESTIONNAIRE

Since the patients' perception is used as a means of measurement, the researcher has to rely on the patients' ability to recall and record the information required. This subjective data may cause errors in the authenticity of the information.

In the treatment group, the four variables that are most likely to be affected by gout (*health; diet; work and active recreation*), showed an improvement while, in the placebo group, other variables were also improved (*sex life; self- expression/improvement and community and civic involvement*).

A definite improvement was found within the treatment group between the first and second consultation as well as between the first and third consultation with regard to *active recreation*.

The researcher believes that although there was an improvement within the placebo group, the improvement will only last while the placebo is administered. The improvement in the treatment group will last much longer, it is believed, regardless of administration of medication.

5.2 ELECTRODERMAL SCREEN TEST

The Acupulse Homeostat machine readings showed a slight aggravation at the second consultation in both groups, followed by improvement in both groups at the third consultation.

Within the treatment group, the aggravation may be explained in terms of the patients' reaction to the medication. Since patients on homoeopathic treatment often show an aggravation before improvement (Lockie and Geddes 1995: 15). This does not however, explain why the placebo group exhibited the same type of reaction.

5.3 URIC ACID TEST

Although there was an improvement in the blood test results of the placebo group, the changes were extremely small and could have been caused by any number of external factors (such as diet).

Within the treatment group, there was an improvement between the first and second consultations, followed by an aggravation (higher blood uric acid levels than the first consultation) at the third consultation. This reaction can be related to possible mobilization of uric acid and it is believed that further blood tests will show a definite and more lasting improvement. This reaction is very similar to what often occurs when a patient is put on chronic prophylactic treatment (Scott 1980).

5.4 COMPARISON BETWEEN EDST AND UAT RESULTS

Both type of tests showed the same general trend within the treatment and placebo group (improvement and aggravation). Although the general trend is the same, there seems to be no correlation between the values measured. This indicates that, although the machine is a valuable instrument in detecting abnormality, it is not accurate enough to replace blood tests as a measurement of blood uric acid level.

5.5 POWER ANALYSIS

Power analysis is a measure of how sensitive a test is and thus how relevant the research undertaken. The results obtained from the power analysis are affected by the sample size, the accuracy of the measurements taken in the study and the level of significance of the study.

The power of non-parametric tests is usually low because of the small sample size, indicating that results obtained from non-parametric tests are not necessarily reliable.

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 CONCLUSION

The aim of this study was to determine the effectiveness of homoeopathic simillimum treatment of acute arthritis in primary gout.

Although the blood uric acid levels were not lowered to normal levels, there were definite changes in these levels, showing that the treatment did have an effect on blood uric acid levels.

The Acupulse homeostat machine can be useful in determining the presence of an abnormality and may also be useful in indicating what further diagnostic tests need to be done.

The fact that there was a clinical change in all groups treated, shows that the treatment used did have an effect. This warrants further research as set out below.

6.2 RECOMMENDATIONS

Should further studies be done, it is suggested that a few changes be made.

The research period should be increased to determine whether the blood uric acid level would stabilize and to determine the long term results of homoeopathic treatment. Medication should also be discontinued in both groups once an improvement is found, as this might reveal the difference between the treatment and placebo groups.

The fact that the study was a double blind study made it difficult to prescribe during follow-up consultations as it was impossible to know whether the patient was in fact on placebo or just not responding to the homoeopathic remedy.

The questionnaire should be changed in such a way so as to exclude the variables that are not relevant to primary gout seeing as these had very little statistical value.

A larger sample size should be used in order to obtain more accurate and statistically valuable results.

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APPENDIX A

The American Rheumatism Association proposed criteria for acute arthritis of primary gout (Wallace et al 1977):

1. More than one attack of acute arthritis
2. Monoarthritis attack
3. Redness observed over joints
4. First metatarsophalangeal joint painful or swollen
5. Unilateral first metatarsophalangeal joint attack
6. Unilateral tarsal joint attack
7. Hyperuricaemia

Six of the above criteria must be present for a diagnosis of gout.

APPENDIX B

Illness intrusiveness ratings scale (Lorig, 1996: 60.)

The following items ask about how much your illness and/or its treatment interfere with different aspects of your life. Please circle the one number that best describes your current life situation. If an item is not applicable, please circle the number one (1) to indicate that this aspect of your life is not affected very much. Please do not leave any item unanswered. Thank you.

How much does your illness and/or its treatment interfere with your...

1. Health

Not very much 1 2 3 4 5 6 7 very much

2. Diet (i.e. the things you eat and drink)

Not very much 1 2 3 4 5 6 7 very much

3. Work

Not very much 1 2 3 4 5 6 7 very much

4. Active recreation (e.g. Sports)

Not very much 1 2 3 4 5 6 7 very much

5. Financial situation

Not very much 1 2 3 4 5 6 7 very much

6. Relationship with your spouse (girlfriend or boyfriend if not married)

Not very much 1 2 3 4 5 6 7 very much

7. Sex life

Not very much 1 2 3 4 5 6 7 very much

8. Family relations

Not very much 1 2 3 4 5 6 7 very much

9. Other social relations

Not very much 1 2 3 4 5 6 7 very much

10. Self-expression/self-improvement

Not very much 1 2 3 4 5 6 7 very much

11. Religious expression

Not very much 1 2 3 4 5 6 7 very much

12. Community and civic involvement

Not very much 1 2 3 4 5 6 7 very much

APPENDIX C

Information Sheet

Gout is a chronic condition that effects many people and can be very limiting. Although treatment used by medical doctors is very effective, it usually has to be taken for the rest of the patients' life. This research will investigate the efficacy of homoeopathy in the treatment and control of gout. In order to do this, I need patients who have gout to join my research group for a period of six weeks. During the six weeks, the patients will be required to come in for a consultation, fill in a questionnaire and go for a blood test every two weeks (all will be done free of charge).

The patients will be divided into two groups, a trial group and control group. The control group will receive treatment at the end of the research period.

Patients will be required to commit themselves to the research for the full six weeks. During this period, no drastic lifestyle changes should be made (especially regarding diet) as this might influence the outcome of the research.

If the results of the research are positive, it will mean that patients with gout can use homoeopathy for the treatment and control of their gout. This will be more cost effective and has very little, if any side effects.

Thank you for taking time to join my research.

Riette Smulders

APPENDIX D

Informed Consent Form

(To be completed in duplicate by patient/subject*)

*Delete whichever is not applicable.

TITLE OF RESEARCHPROJECT:

The homoeopathic simillimum treatment of acute arthritis in primary gout in terms of the illness intrusiveness scale, blood uric acid levels using the uricase conversion method as well as the Acupulse Homeostat machine.

NAME OF SUPERVISOR:

Dr G McDavid

NAME OF RESEARCH STUDENT:

Henriette Smulders

DATE: _____

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 | |
| b) without having to give a reason for withdrawing | |
| c) without affecting your future care. | |
| 9. Do you agree to voluntarily participate in this study? | Yes/No |

PATIENT/SUBJECT* Name _____ Signature _____
(In block letters)

PARENT/GUARDIAN* Name _____ Signature _____
(In block letters)

WITNESS* Name _____ Signature _____
(In block letters)

RESEARCH STUDENT Name _____ Signature _____
(In block letters)