HOMOEOPATHIC TREATMENT OF OSTEOARTHRITIS IN TERMS OF PATIENT PERCEPTION AND CLINICAL MANIFESTATIONS.

HOLTON JAMES KAUFMANN

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

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DECLARATION

I, Holton James Kaufmann, do hereby declare that this research dissertation is my own work and has not been presented for any other diploma of another university or technikon.

Signed:

APPROVED FOR FINAL SUBMISSION

SUPERVISOR : Dr F J Burger Dsc (Physiology) (US), Dsc (Biochemistry) (PU)

DURBAN

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DEDICATION

To my mother, Theresa Kaufmann

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ABSTRACT

This clinical trial focused on evaluating homoeopathic simillimum treatment of hand osteoarthritis. Emphasis was placed on assessing changes in measurable clinical manifestations and participants pain perception related to this condition.

A double-blind, placebo-controlled protocol was utilized involving 30 participants chosen from respondents to advertising in the Durban newspapers. Participants were randomly assigned to receive homoeopathic simillimum or placebo treatment.

Bilateral antero-posterior-, oblique- and lateral hand and wrist x-ray's were taken to diagnose osteoarthritis. Clinical evaluation utilized the following tools:

1. Collin dynamometer (hand grip-strength)
2. Finger goniometer (degrees of mobility)
3. Circumeter (joint circumference measurements)
4. Aesthesiometer (articular index of joint sensitivity)

The 101-point Numerical Rating Scale (Jensen et al. 1986) was used to test pain intensity and the Short Form McGill pain questionnaire (Melzack 1987) was used to monitor participants pain perception. All tests and questionnaires were repeated monthly over the three month trial duration.

Data was statistically analyzed using the "Statgraphics plus" spreadsheet programme. Intra-group data (placebo initial versus placebo final and treatment initial versus treatment final) was analyzed using the "Wilcoxon signed-rank" test. The "Mann-Whitney U" test was utilised to analyze inter-group data (placebo initial versus treatment initial and placebo final versus treatment final).

Significant improvements occurred in grip strength for the left hand of both placebo and treatment groups (placebo increase = 35.75%, $p = 0.05$ and treatment increase = 17.26%, $p = 0.0117$) and for the right hand treatment group (increase = 47.80%, $p = 0.0117$).

Joint range of motion improved in treatment patients (left hand increase = 5.5%, $p = 0.0104$ and right hand increase = 8.5%, $p = 0.0093$) relating to an average increase of 0.77 degrees for right hand individually affected joints and 0.42 degrees for left hand joints.

Significant inter-group differences were observed in Aesthesiometer measurements of the treatment and placebo groups at both initial and final consultations (initial left hand $p = 0.0125$ and final $p = 0.0394$ and initial right hand $p = 0.0189$ and final $p = 0.0394$). Intra-group analysis indicated a statistically significant reduction in the placebo group sensitivity (left hand $p= 0.0263$ and right hand $p = 0.0223$).

Pain questionnaire analysis yielded a significant intra-group decrease in the treatment group 101-point Numerical Rating Scale scores of 65.01% ($p= 0.072$). No statistical changes emerged from analysis of the Short Form McGill pain questionnaire.

Homoeopathic simillimum treatment of hand osteoarthritis can improve joint range of motion and hand grip strength. This treatment can also improve perceived pain intensity.

It is recommended that further investigation of homoeopathic treatment of osteoarthritis be confined to mono-joints e.g. the knee joint. Also, due to the often slow, insidious progression of osteoarthritis it is recommended that the treatment period be extended to more thoroughly assess the effect homoeopathic treatment has on osteoarthritis.

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DEFINITION OF TERMS

Simillimum:

Simillimum or the law of similars implies a similarity between the toxic and therapeutic actions of a substance. A substance capable of inducing symptoms in a healthy individual used to cure those symptoms in a sick individual is termed "the simillimum". (Jouanny, 1991:12.)

Repertorising:

This is a homoeopathic process whereby symptoms and signs elicited from a patient are matched with relevant remedies containing these symptoms and signs. The remedy with the greatest similarity is chosen as the simillimum. (Fraser 1992.)

Placebo:

A placebo is defined as being any therapy or component of therapy deliberately used for non-specific, psychological, or psychophysiological effects, or that is used for its presumed specific effect, where that therapy has no specific activity for the condition being treated (Richardson 1989:34).

CHAPTER ONE INTRODUCTION

Osteoarthritis is the most common form of arthritis irrespective of the type of population considered (Badley 1995). It is a common cause of severe, disabling and intractable pain (Harkness et al. 1985:215).

March and Brooks (1996) suggest that osteoarthritis provides the greatest challenge of all the rheumatic diseases and conclude that with an ageing population it will become the most prevalent disease in modern society generating enormous costs. Gabriel et al. (1995) found that osteoarthritic patients incur substantially increased medical costs for arthritis care and that these patients also have significantly higher levels of work disability compared to age and sex related subjects in similar communities without osteoarthritis.

Allopathic treatment of osteoarthritis follows a symptomatic approach and is primarily directed at pain relief (Harkness et al. 1985:222). Non-steroidal anti-inflammatory drugs (NSAID's) are commonly used in the (allopathic) treatment of osteoarthritis (David et al. 1992).

March and Brooks (1996) claim that some commonly used NSAID's may actually hasten radiological deterioration of osteoarthritis. Despite their therapeutic benefits, Blower (1996) states that NSAID's are associated with serious gastrointestinal side effects including ulceration, haemorrhage and perforation.

Homoeopathic treatment is reactive. Its therapies act together with the body's reactions and attempt to stimulates the body's defence mechanisms so as to make them work more effectively. Emphasis is placed on individualisation of treatment by finding a specific stimulant to the organism. (Jouanny 1991: 11-22.)

Despite the significant and increasing prevalence of osteoarthritis, there has been relatively little research into the condition by either the allopathic or homoeopathic communities. Hutton (1994:85) states: "Osteoarthritis has for too long been regarded as a degenerative dead end, uninspiring, unimportant and as a result uninvestigated".

Previous research into homoeopathic treatment of rheumatic conditions has compromised both scientific and homoeopathic approaches (Fisher 1990). The trial conducted by Shipley et al. (1983) comparing homoeopathic Rhus toxicodendron 6X with the NSAID Fenoprofen in the treatment of osteoarthritis was criticised for not following the homoeopathic simillimum principle. Fisher (1990) states that the total number of studies into homoeopathic treatment of rheumatic conditions is small, that the trials themselves have been small in scale and that none have been immune from criticism.

This study aims to combine homoeopathic and scientific principles by investigating homoeopathic simillimum treatment of osteoarthritis using the established scientific double-blind trial method with placebo control.

The purpose of this investigation is to evaluate the effect of homoeopathic simillimum treatment of osteoarthritis of the hands in terms of pain perception and clinical manifestations in order to determine how homoeopathic treatment affects this condition.

CHAPTER TWO REVIEW OF THE RELATED LITERATURE

2.1 HISTORY

Osteoarthritis is an age old disease. Joint changes typical of osteoarthritis have been found in fossilised skeletons of dinosaurs and other prehistoric vertebrate creatures. Egyptian mummies have shown signs of osteoarthritis and examination of 400 medieval soldiers revealed osteoarthritic changes in approximately 50 % of the skeletons. (Harkness et al. 1985:215.) Socrates in ancient Greece listed arthritis as a common disease (Hindshaw 1985).

Perhaps because osteoarthritis is an age old disease, it has become accepted as an expected and natural part of the ageing process and therefore little research appears to have been conducted into the condition. We have already cited Hutton (1994:85) who states: "Osteoarthritis has for too long been regarded as a degenerative dead end, uninspiring, unimportant and as a result uninvestigated". Badley (1995) claims that one of the reasons why osteoarthritis research and information is relatively neglected is due to a dearth of explicit information about its effect on the general population.

Great potential therefore exists for research into all facets of osteoarthritis from basic research into the causes of the condition to treatment and cure possibilities.

2.2 WHAT IS OSTEOARTHRITIS?

A problem facing present research into osteoarthritis is the lack of an accepted definition of the condition. Croft (1990) states that there is no clear clinical definition of osteoarthritis and that marked changes can be present on x-ray in the absence of symptoms. Hutton (1994) claims that working and communicating on osteoarthritis is confused by the poor definition of the condition which is loosely and widely recognised as a joint disease characterised by the presence of osteophyte's, bone sclerosis and cartilage disintegration.

Dieppe (1995) points out that there are currently two different hypotheses on the nature of osteoarthritis. The widely reported view in medical literature sees osteoarthritis as a group of diseases amenable to cure through scientific discovery. Alternatively, osteoarthritis is seen as a natural phenomenon occurring as part of an evolutionary inheritance and is therefore an acceptable and expected part of pain and disability in the elderly.

Dieppe (1995) states that a recent consensus meeting of rheumatologists failed to define osteoarthritis. This meeting described the condition as a disease process involving a disturbance of the normal balance of degradation and repair in the articular cartilage and sub-chondral bone. From this disturbance, areas of morphological damage occur

which occasionally result in clinical problems such as pain and instability.

Dieppe et al. (1995) claim that osteoarthritis should not be considered as a single disease entity and that osteoarthritis of different joints should be regarded as entirely separate disorders.

In the absence of an accepted definition of the condition, Jacobsson (1996) notes characteristics of osteoarthritis which include pain on movement, radiographic findings including degenerative features (marginal osteophytes, subchondral cysts and loose bodies), reparative features (marginal osteophytes, subchondral sclerosis) and inflammatory features (joint effusions, bursar extensions).

Dieppe (1995) describes the condition as a mixture of degradative and reparative processes which occur in the articular cartilage and subchondral bone, and which are associated with capsular fibrosis, marginal osteophyte formation and low grade inflammation. Although these processes are linked, Dieppe concludes that it is not known which are primary or secondary processes. Moskowitz (1993:1735) states that osteoarthritis is defined as primary or idiopathic in the absence of any known underlying predisposing factors and as secondary where identifiable underlying local or systemic pathogenic factors exist.

2.3 INCIDENCE

Badley (1995) states that osteoarthritis is the most prevalent form of arthritis irrespective of the type of population considered. Spector and Hochberg (1994) concur and add that osteoarthritis is the most common form of arthritis in the developed countries.

Hart et al. (1994) estimate that osteoarthritis affects the hand joints of some 70% of men and women aged 65 years and over. These authors also feel that osteoarthritis is far more common than other forms of arthritis in the general population and that accurate diagnosis therefore depends more importantly on distinguishing osteoarthritis from people with no joint disease whatsoever.

Cicuttini and Spector (1996) found osteoarthritis to be the most frequent cause of musculoskeletal disability in developed countries. These authors also found that primary generalised osteoarthritis is the most common form of inherited osteoarthritis.

According to Jacobsson (1996) osteoarthritis is the most common joint disorder. Jacobsson (1996) states that prevalence increases with age and that in women 80 years and older, radiologically defined osteoarthritis is found in over 70% of distal inter-phalangeal joint x-ray's. Moskowitz (1993:1737) claims that roentgenological degenerative

changes can be observed in weight bearing joints in 90% of all persons over the age of 40 although clinical symptoms are generally absent.

Radiographic studies of persons from the age of 15 have shown that until the age of 54, men and women have a similar distribution and extent of osteoarthritic joint involvement. After this age osteoarthritis is found to be more severe and more generalised in women. Also, in people above the age of 55, the distal and proximal inter-phalangeal and the first carpometacarpal joints are more frequently affected in women whereas in men the hips are more commonly affected. (Moskowitz 1993:1737.) Cooper (1995) states none-the-less that osteoarthritis is second only to ischaemic heart disease as a cause of work related disability in men over the age of 50.

The actual number of people with radiological signs of osteoarthritis are likely to have increased in recent decades as the proportion of older people in the population has risen (Croft 1990).

The frequency of occurrence of this condition may ironically be partially responsible for the complacency noted towards this condition in terms of a relative lack of research into osteoarthritis and the passive, symptom related approach towards the management of the condition.

2.4 ETIOLOGY

Cauley et al. (1993) state that despite the identification of multiple risk factors for the development of osteoarthritis, the etiology remains unknown and is likely to be multifactorial.

Autopsy studies show that degenerative joint changes begin in the second decade (Moskowitz 1993:1737). The largest influence on the occurrence of osteoarthritis according to Croft (1990) is age.

Identified risk factors associated with the development of osteoarthritis include high intensity impact loading exercise (Buckwalter 1995). Cauley et al. (1993) found a higher incidence of hand osteoarthritis in patients with no high school diploma. According to Felson (1995) there is an increased risk for the development of osteoarthritis of the knee and probably the hands and the hips in overweight people.

O'Driscoll and Jayson (1982) suggest that the lack of sensitivity to noxious stimuli found in hands allows for hand joints to be easily damaged and thereby encourages development of degenerative changes.

2.5 JOINT STRUCTURE AND PATHOLOGY

An understanding of osteoarthritis requires an understanding of the articular cartilage primarily affected by osteoarthritis. This cartilage provides the smooth friction-free articular surface through which load is evenly distributed onto the subchondral bone. This cartilage is composed of a framework of collagen fibres with "spring" provided by large proteoglycan molecules which attract water to maintain the cartilage structure. Approximately 70% of cartilage tissue mass is water. The balance between the swelling with water and the tension created by the extended collagen network gives the tissue its elastic and compressive qualities, enabling it to function as a durable weight bearing surface. Embedded in the cartilage is a sparse population of cells, the chondrocytes, whose function is to synthesise and lay down the highly organised matrix. These cells also produce and secrete enzymes which maintain the cartilage by a slow process of repair and renewal. (Hardingham et al. 1992.)

Compounding the problem of basic osteoarthritis research is a poor understanding of the pathological processes occurring in osteoarthritis. Hutton (1994) states that the ability of a biological system to adapt to change adds to the confusion regarding the development of osteoarthritis. Hutton suggests that this adaptive response may result in the development of osteoarthritis if it is maladaptive thereby resulting in

joint failure. Conversely he suggests that the ability to change of biological systems may also be regarded as adaptive resulting in joint stability as is evidenced by a high prevalence of asymptomatic osteoarthritis.

Hutton and Vennart (1995) describe striking hydration changes which occur in osteoarthritis cartilage. Experimental evidence and analysis of osteoarthritis samples by these authors show an increase in the water content of cartilage in the initial stages of the disease. In severe disease a loss of cartilage water content is noted.

The joints most commonly affected with osteoarthritis include the distal and proximal inter-phalangeal joints, the first metacarpal joints, the hip and knee joint, the first metatarso-phalangeal joints and the lower lumbar and sacral vertebrae (Moskowitz, 1993:1737.)

Data relating to the course of hand osteoarthritis is provided by the Baltimore longitudinal study of ageing which showed that progression of osteoarthritis is faster in the distal than in the proximal inter-phalangeal joints of the hands (Hochberg 1996). This study also suggested a burnout phenomenon with slower disease progression occurring in joints with a greater baseline severity than in those joints with a milder disease.

2.6 PAIN

The international association for the study of pain defines pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" (Large 1996:340).

Moskowitz (1993:1739) cites pain as being the cardinal symptom of osteoarthritis. Cooper (1995) considers joint pain and functional impairment to be the two most important clinical sequelae in studies of osteoarthritis. According to Hart et al. (1994) osteoarthritis of the hand is an important cause of pain and minor disability and also often indicates a systemic tendency to osteoarthritis.

Osteoarthritic pain initially occurs after joint use and is relieved by rest and is typically aching and localised. Pain onset is generally insidious and there is a lack of association with systemic manifestations. With disease progression, pain may occur after minimal motion or even at rest. Sleep disturbances from pain occur in advanced stages. (Moskowitz, 1993:1939.)

Pain in osteoarthritis is frequently experienced without any obvious physical signs (Large 1996). Despite osteoarthritis being a common cause of severe, disabling and intractable pain, Harkness et al. (1985:217) state that the cause of the pain remains obscure as the articular cartilage which is

primarily affected by osteoarthritis is devoid of nerves. These authors also found that some patients with advanced osteoarthritis are asymptomatic whereas others experience degrees of pain ranging from mild to considerable.

Several factors associated with osteoarthritis may cause pain: Osteophyte formation at joint margins may cause an elevation of periosteum and thereby cause pain. Excessive strain on ligaments surrounding unstable osteoarthritic joints are a possible cause of pain. Inflammation may be associated with osteoarthritis and can be a cause of pain. (Harkness et al. 1985:217.)

Six types of osteoarthritic pain have been classified:

1. Immobility pain, described as an unpleasant aching and affecting any joint but particularly the knees, thumb bases, neck and hip. This pain is often the first symptom of osteoarthritis and may be relieved by massage.
2. Weight-bearing pain, generally occurs at later stages of the disease and affects weight bearing joints such as the spine, hips and knees.
3, Movement pain, experienced when stretching the fibrosed, contracted joint capsule.
4. Pain related to inflammation which is often associated with morning stiffness, joint line tenderness and effusions.
5. Pain due to trauma.
6. Pain related to or exaggerated by psychogenic factors. (Wall and Melzack 1985:216.)

Wall and Melzack (1985:217) cite extensive radiological surveys conducted by Lawrence et al. (1966) which showed that pain occurs in less than 10% of cases where radiological evidence shows signs of early osteoarthritis. It is therefore important to remember that while pain may be regarded as an important and intrinsic part of osteoarthritis research, care must be taken not to exclude research volunteers who show clinical evidence of the disease and yet are pain free.

2.7 EFFECTS OF OSTEOARTHRITIS

According to Badley (1995) long term disability resulting from osteoarthritis is associated with a substantial effect on daily life. Badley claims that problems encountered by osteoarthritis sufferers include mobility difficulties, dependence on others, difficulties experienced with everyday living activities, social isolation, low income and restricted leisure and recruitment possibilities.

Hochberg et al. (1995) in a study of 902 physician diagnosed osteoarthritic women aged 65 and above, found the condition to be significantly associated with difficulties in the following thirteen areas: arm raising, lifting up to 10 pounds, walking 2-3 blocks, bathing or showering, climbing 10 steps, grasping objects, getting in or out of a bed or chair, dressing, using the toilet, preparing meals, doing

personal shopping and heavy and light housework. Lane (1996) states that osteoarthritis is the major cause of activity limitation in the elderly.

Ahern et al. (1995) found that patients with osteoarthritis are less preoccupied with their illness and its effects on their health than patients with rheumatoid arthritis and also tend to be more preoccupied with somatic symptoms and their severity. These patients generally related to their illness as the only cause of their distress and problems in life.

Large (1996) found that people with chronic musculo-skeletal pain caused by conditions such as osteoarthritis commonly avoid activities that they think will exacerbate their pain. Large furthermore considers pain to cause adverse psychosocial effects including a sense of alienation, problems with depression and anger, a loss of bodily integrity and sense of self and in severe cases an increased suicidal tendency.

Disability and handicap are considered by Dieppe (1995) to be major risk factors associated with osteoarthritis because this condition is often asymptomatic and little is known about the cause of pain in osteoarthritis.

Despite osteoarthritis frequently being asymptomatic, the literature reviewed points to a wide variety of effects

osteoarthritis can have on daily life. This indicates a need for holistic management to form part of the care and treatment of osteoarthritis sufferers.

2.8 ALLOPATHIC TREATMENT

Allopathic management of osteoarthritis is symptomatic and is directed mainly at pain relief (Harkness et al. 1985:222.). These authors state that there are as yet no agents capable of preventing or reversing the pathological changes of osteoarthritis.

Non-steroidal anti-inflammatory drugs (NSAIDs) form the mainstay of physician prescribed drugs to patients with rheumatoid- and osteo- arthritis. A recent study involving six European countries (Britain, Germany, France, the Netherlands, Italy and Sweden), found that 77% of osteoarthritic patients indicated that NSAIDs were effective or moderately effective in controlling their condition. (Emery 1996.)

2.9 ALLOPATHIC MEDICATION SIDE EFFECTS:

According to March and Brooks (1995) suggestions have been put forward that some commonly used non-steroidal anti-inflammatory drugs (NSAIDs) may actually hasten radiological

deterioration of osteoarthritis. David et al. (1992) acknowledge that NSAIDs are commonly used in the treatment of osteoarthritis. These authors state, however, that some NSAIDs are thought to accelerate the progression of osteoarthritis by actively precipitating cartilage destruction. In particular, inhibition of cartilage proteoglycan synthesis has been observed in in vitro testing with salicylates and indomethacin. It is thought that this inhibition affects the increased metabolism found in osteoarthritis cartilage. Khoker and Dandona (1988) found accelerated osteoarthritic destruction of hip joints in patients treated with NSAIDs like indomethacin. These authors also found aspirin to have profound effects on cartilage and bone metabolism and the quality of collagen formation.

Despite their therapeutic benefits, NSAIDs are associated with serious and sometimes fatal gastrointestinal side effects including ulceration, haemorrhage and perforation (Blower 1996). Doube and Morris (1988) state that non-steroidal anti-inflammatory drugs commonly cause dyspepsia. According to these authors, the factors involved in this are not fully understood although direct injury to gastric mucosa and inhibition of prostaglandin-dependant cyto-protective mechanisms are implicated.

Gastrointestinal side effects such as nausea, vomiting and dyspepsia are established aspirin side effects.

Approximately 0.2% of patients taking aspirin will develop hypersensitivity reactions including respiratory symptoms (wheezing and asthma), anaphylaxis with shock, urticaria or angioedema, or combinations of the above. (McCarty and Koopman 1993:579.)

McCarty and Koopman (1993:579) also claim that hepatotoxic and nephrotoxic effects, evidenced by abnormal liver and kidney function tests, have been found in patients taking aspirin and other NSAID medications.

In a study of 107 osteoarthritic patients participating in a trial concerned with illness behaviour, Ahern et al. (1995) found that 37 participants withdrew due to the following allopathic drug treatment related reasons: well defined toxic reactions, including gastro-intestinal bleeding (three patients), skin rashes (one patient), moderate to severe epigastric pain (four patients), poorly defined side effects such a vague abdominal pain (31 patients), headaches (11 patients), fatigue (four patients), malaise (five patients), light-headedness (seven patients) and anorexia (seven patients).

Taylor (1989) states that in a study where 23 osteoarthritic patients were treated with aspirin, a decrease in appetite was noted placing these participants in a potential nutritional risk.

Lockie and Geddes (1995:7) suggest that many people are turning to homoeopathy as a reaction to unacceptable side effects and spiralling costs associated with allopathic medicines. Research into the feasibility of using homoeopathic treatment for conditions like osteoarthritis is therefore becoming more and more necessary.

2.10 HOMOEOPATHIC RESEARCH and TREATMENT:

Fisher (1990) has pinpointed three areas of research into homoeopathic treatment of rheumatological diseases that need development:

1. Efficacy research: is homoeopathic treatment effective in rheumatological conditions? In other words, does the homoeopathic treatment give benefit when compared to another treatment. Fisher suggests the use of placebo control to answer this question.
2. Developmental research: determining which homoeopathic medicine or prescribing strategy is most effective in which situation. This is of particular importance when considering the complexity of homoeopathic treatment. Fisher suggests that developmental research should precede efficacy research to ensure that the efficacy of the optimal treatment is being researched.
3. Basic research: in other words, how does the treatment work? This is the homoeopathic grey area whereby the physiological processes that homoeopathic treatment

affects are not understood. Fisher suggests that it is more important to first find out if homoeopathic treatment is effective in managing rheumatic conditions. If this question is positively answered, the need to find out how the treatment works will arise.

It has already been established, following Hutton (1994:85), that osteoarthritis has too often been considered to be a "degenerative dead end, uninspiring, unimportant and as a result uninvestigated". A cursory review of the related literature revealed a relative dearth of homoeopathic and allopathic research into the osteoarthritic condition compared to rheumatoid arthritis research.

Possible reasons for the apparent lack of research into osteoarthritis compared to rheumatoid arthritis investigations include the perception that osteoarthritis is an accepted part of the ageing process requiring only symptomatic treatment (Hutton 1994). Rheumatoid arthritis is the most common form of chronic inflammatory joint disease which in its typical form is symmetrical, destructive and deforming (Edwards and Bouchier 1991:762). Rheumatoid arthritis is a systemic disease and manifestations include haematologic, pulmonary, neurologic and cardiovascular involvement (Gilliland and Mannik 1974:1987). Osteoarthritis although the most common form of the rheumatic conditions (Badley 1995) has no systemic involvement and inflammation

is usually minor and secondary (Edwards and Bouchier 1991:798). Rheumatoid arthritis can therefore be considered to be more severe than osteoarthritis.

Research into the homoeopathic treatment of rheumatoid arthritis can none-the-less highlight areas of difficulty encountered in the homoeopathic treatment of rheumatological conditions. In particular, criticism levelled against previous homoeopathic research into the treatment of rheumatoid arthritis should be noted.

Fisher (1990) cites research conducted by Gibson et al. (1978) involving 195 patients with rheumatoid arthritis who were inadequately controlled on non-steroidal anti-inflammatory (NSAID) medicine. Participants were divided into groups receiving homoeopathic treatment in addition to their NSAID medicine or receiving additional high dose enteric-coated aspirin. Placebo control was used for both groups. Impressive results were found in the homoeopathically treated group with 42.6% of these participants having improved sufficiently to have stopped all other medication at the end of the twelve month research period. This research was criticised, however, on the grounds that whilst homoeopathic prescribers were free to prescribe any homoeopathic medicine, conventional doctors were only able to prescribe varying doses of aspirin. Furthermore, the sucrose-sugar based placebo medication was

easily recognisable thus making the trial not truly double-blind.

Shipley et al. (1983) conducted a three-way cross-over, double-dummy, double-blind trial on osteoarthritis comparing homoeopathic Rhus tox in a 6X potency with an allopathically treated group (using the non-steroidal anti-inflammatory drug Fenoprofen). This method was used because homoeopathic and conventional medicines differ in taste and appearance and for the trial to be truly blind, it was necessary for two placebos to be used. Each patient therefore received three different combinations: active Rhus toxicodendron plus placebo Fenoprofen, placebo Rhus toxicodendron plus active Fenoprofen, and double placebo. Thirty three patients with radiologically diagnosed osteoarthritis of the hips and knees were assigned to receive two week treatment periods of the three treatment combinations on a random basis. Assessment was based on visual analogue scale (VAS) scores of pain at rest, on movement and at night.

The results were negative with respect to the homoeopathic medicine in that no significant differences were found between the VAS scores of placebo and homoeopathically treated patients. Highly significant improvements emerged when participants were treated with Fenoprofen. Rhus toxicodendron 6X was found to be different to placebo treatment, however, in that five participants experienced exacerbatory symptoms while taking this medicine. In two cases these symptoms were severe enough to cause withdrawal

from the trial. No aggravating symptoms occurred in the other groups.

Several criticisms can be directed against this trial from a homoeopathic viewpoint: The relatively low potency 6X Rhus toxicodendron (a one in one million dilution of the substance), while satisfying allopathic conditions of using a medicine where actual substance is present, limits the homoeopathic action to the physical level. (Fraser 1993). Boyer (1994) recommends the use of a 9C potency Rhus toxicodendron (a one in ten to the power of minus seventeen dilution).

The choice of a single remedy, again to satisfy allopathic criteria of demonstrating the efficacy of a known and solitary substance, is contrary to homoeopathic philosophy where treatment must follow the principle of simillimum (Jouanny 1991:15). In homoeopathic treatment Rhus tox is indicated in cases of "painful stiffness relieved by motion" (Jouanny 1984:343-346) and would thus not be indicated or beneficial in cases of arthritis where "shooting, acute, piercing pains are made worse by the slightest movement." (Jouanny, 1984:76-79). In this instance the simillimum is more likely to be Bryonia alba.

Another drawback of this research was the relatively short two week treatment periods used. Lockie and Geddes (1995:7)

suggest that homoeopathic treatment is not suitable for people in search of an instant cure and that effective treatment requires will power to stick to the treatment plan. In light of this, a two week treatment period is considered to be insufficient.

Fisher (1990:37) states: "There is always a trade off between scientific rigour and realism. As the credibility of homoeopathic therapy is increasingly established we will see a shift towards trials of homoeopathy as it is practised, as opposed to trials in which the homoeopathic method is cramped by the methodological demands. These more realistic trials will be less rigorous in the strict sense, but they will give a clearer picture of the capabilities of homoeopathy. More importantly they will be of greater clinical relevance."

Although scientific research concerning the homoeopathic treatment of conditions like osteoarthritis is bound to encounter problems similar to those pointed out in the literature, the benefits of establishing homoeopathic credibility within the medical and scientific communities provide encouragement and motivation to overcome these problems.

CHAPTER THREE MATERIALS AND METHODS

3.1. STUDY DESIGN

The double-blind, placebo-controlled protocol was followed. Participants were randomly divided into two groups by the dispensing pharmacist, one half receiving placebo medicine and the other half receiving homoeopathic medicine. The researcher was unaware of which patients were receiving placebo medication or homoeopathic medication until the conclusion of the study.

3.2. THE SUBJECTS

Advertisements for patients were placed in the major Durban newspapers and flyers were posted on shopping centre notice boards and on old-age home notice boards.

Respondents were accepted provided that they did not fall into one of the following categories:

i) individuals suffering from hand joint diseases other than osteoarthritis.

ii) individuals who took prescribed medication or "over the counter" medication for their osteoarthritis.

A sample of thirty participants was chosen from respondents who presented at the first interview with signs and symptoms most likely to indicate a positive diagnosis of osteoarthritis. Indicators included visual examination of the joints for typical arthritic nodosities and deformations and verbal questioning relating to pain induced by the osteoarthritis. Participants with medically diagnosed osteoarthritis were also accepted.

The research purpose and procedure was explained to participants and opportunity was given for participants to ask questions. Participants were then asked to complete the "Informed Consent Form" (Appendix L).

3.3. INTERVENTIONS

A full medical and homoeopathic case history of each participant was taken (Appendix M). This was followed by a full medical examination.

Each case was repertorised and checked by a qualified homoeopath.

Once confirmation of an osteoarthritis diagnosis was received with the first x-ray report, the prescription was given to the pharmacist, a neutral member in the study. The pharmacist allocated participants into groups

receiving either homoeopathic medication or placebo medication by using tables of random numbers.

Medicines were dispensed to patients with standardised instructions regarding storage and administration. Participants were advised to keep medication away from sunlight and other heat sources and also away from strong smelling substances e.g. perfumes and camphorated products. Participants were advised to take medication fifteen minutes before meals and were asked also not to take medication within fifteen minutes of smoking, brushing teeth or drinking any liquids other than water. (Fraser 1993.)

Participants were required to attend follow up appointments at monthly intervals for the duration of the trial. The case history and physical examination of each participant was re-evaluated to determine whether to continue with the prescribed medication or to alter it in accordance with new or changing symptomatology.

Altered scripts were again checked by a senior homoeopath before being prepared and dispensed by the pharmacist.

3.4. MEASUREMENTS

Dieppe et al. (1995) state that pain measurements and functional tests should be used to assess the putative symptomatic treatment of osteoarthritic medications. Disease modification should be measured using anatomical changes in the joint which can be observed through chondroscopy, radiography, M.R.I. and other imaging techniques.

3.4.1. MEASUREMENT OF CLINICAL MANIFESTATIONS

3.4.1.1. Hand grip-strength

A "Collin" dynamometer was used to take grip - strength measurements of both hands. Only the first reading for each hand was recorded.

The "Collin" dynamometer was chosen in preference to the use of an inflated blood-pressure cuff for the measurement of hand grip strength. Unsworth et al. (1990) state that the common use of inflated blood-pressure cuffs for measuring hand grip-strength is affected by:

a. Large hands: these were found to produce a lower pressure than smaller hands even when grip strength was the same in both.

b. The use of different volume or diameter bags. A greater rise in grip-strength pressure occurs when using small bags compared to large bags due to the gas law for adiabatic compression of air.

c. The use of different starting pressures.

d. Different squeezing techniques.

The "Collin" dynamometer is a calibrated, spring compression device used to measure hand grip-strength. It is a flat device which fits easily into the palm of all hand sizes and is sensitive to weak grip-strength. The dynamometer is calibrated from zero and the unit of measurement is kilograms (de Koning 1997).

3.4.1.2. **Joint range of motion measurements**

A finger goniometer designed primarily for measuring degrees of motion of hand joints was used.

3.4.1.3. **Articular index of joint sensitivity**

An "aesthesiometer" was used to quantify an articular index of joint tenderness (Fisher 1990). O'Driscoll and Jayson (1982) assert that "pressure algometers" have been used since Victorian times to measure pain

threshold. An "aesthesiometer" allows the surface sensibility of the joint to be expressed in a form that can be read off the scale of the aesthesiometer. The gradation marks on the aesthesiometer have no particular unity and are merely a means of providing a more objective measurement (Luykx 1997).

3.4.1.4. **Circumference measurements**

A "circumeter" (a small orthopaedic inertia-reel circumference meter) was used to take measurements of the thickest part of the affected joints. Measurement is in centimetres.

All measuring equipment was purchased from "Medio-Tronics", Johannesburg. Equipment was manufactured by "Enraf-Nonius", Delft, Netherlands.

3.4.2. **EVALUATION OF PAIN PERCEPTION**

Moskowitz (1993:1739) cites pain as being the cardinal and most common symptom of osteoarthritis. Pain measurement has been used in more than 50% of non-steroidal anti-inflammatory drug trials of osteoarthritis treatment (Bellamy 1995).

The short-form McGill pain questionnaire (Melzack 1987) and the 101-point Numerical Rating Scale

(Jensen et al. 1986) were used to assess participants pain perception due to their osteoarthritis.

3.4.2.1. **The McGill pain questionnaire**

Richardson (1989) asserts that the McGill pain questionnaire is widely used in the field of pain assessment. Burckhardt and Bjelle (1994) state that the McGill pain questionnaire has been extensively used over the last fifteen years in a wide variety of settings and conditions to describe the pain of rheumatoid- and osteo- arthritis. Basmajian and Nyberg (1993:75) find that the McGill pain questionnaire provides a calculable means for measuring pain statistically and that therapeutic interventions in painful conditions can be evaluated with reasonable clinical reliability using the McGill pain questionnaire because it has been shown that each category in the questionnaire demonstrates internal consistency as well as significant correlations between categories. Large (1996) claims that the McGill pain questionnaire provides a complementary adjectival description to simple measures of pain intensity and that research on this questionnaire suggests that different significance is attached to words with a "sensory" description as opposed to words with "evaluative" or "affective" descriptions. Richardson (1989:433) states that the affective component of pain can be measured both with

the McGill pain questionnaire and the visual analogue scale.

The short-form McGill Pain Questionnaire (SF-MPQ) was used in this study. Arthritic pain together with labour, menstrual, headache, phantom, post-herpetic, dental, cancer and lower-back pain was used to develop the SF-MPQ. The SF-MPQ has shown a consistently high correlation with scores obtained from the standard form McGill Pain Questionnaire and the SF-MPQ is sufficiently sensitive to demonstrate differences in pain perception following treatment. The SF-MPQ is used in situations where the standard McGill Pain Questionnaire takes too long to administer. (Melzack 1987.)

The SF-MPQ was chosen by the researcher because this study concentrated exclusively on hand pain and it was felt that the standard form McGill Pain Questionnaire in which participants are asked to circle on a body diagram all areas currently affected by pain might have confused the participants ability to rate hand pain only.

3.4.2.2. **The 101-point Numerical Rating Scale**

The 101-point Numerical Rating Scale (NRS-101) was used to obtain a subjective measure of pain intensity. The NRS-101 is considered to be extremely

simple to administer and score and unlike the visual analogue scale, difficulty with the scale does not appear to be associated to age. (Jensen et al. 1986.)

3.4.3. X-RAY EVALUATION OF OSTEOARTHRITIS SEVERITY

Buckland-Wright (1994) asserts that radiography is important in the diagnosis of osteoarthritis and that excellent features of bony structure can be visualised with plain film radiography, especially joint space narrowing which is thought to reflect cartilage loss. These characteristics together with generally universal availability of radiographic equipment has resulted in its use in confirming clinically suspected osteoarthritis.

March and Brooks (1996) find that the study of cartilage structure has greatly improved with the advent of magnetic resonance imaging despite poor resolution and tissue discrimination capabilities currently associated with the imaging of bone. The expense of this technique however precludes it from general use.

Kellgren and Lawrence (cited by Jacobsson 1996) devised a standardised method of radiologically defining osteoarthritis in 1957. This method was adopted by the World Health Organisation in 1961.

Jacobbson (1996) states that a single postero-anterior radiograph of the hand and wrist is adequate for scoring radiographic hand osteoarthritis.

Participants were given x-ray request forms and were asked to have the x-ray's taken within one week. All x-ray's were taken and interpreted by staff at Fannin, Bortz and partners (radiologists) Durban. Antero-posterior-, oblique- and lateral view x-ray's of the affected hands and wrists were taken and assessed for osteoarthritis severity using the scale devised by Kellgren-Lawrence.

3.5. STATISTICAL PROCEDURES

3.5.1. Data relating to apparatus testing

Apparatus measurements were recorded next to the relevant joint on a traced copy of the hand. Different pen colours were used at each visit to ensure correct differentiation between visits.

Data was statistically analyzed using the spreadsheet programme "Statgraphics Plus". Intra-group analysis utilizing the "Wilcoxon signed-rank" test compared placebo group initial data versus placebo group final data and treatment group initial data versus treatment group final data. Inter-group analysis (placebo initial data versus

treatment initial data and placebo final data versus treatment final data) was conducted using the "Mann-Whitney U" test.

The mean for data obtained from test apparatus at each visit was calculated for both the treatment and placebo group and data is represented in tables in the results section.

3.5.2. Data relating to pain perception questionnaires

Data was captured from printed copies of the short-form McGill Pain Questionnaire (Melzack 1987) and the 101-point Numerical Rating Scale (Jensen et al. 1986) which were dated and completed by participants.

Data from the short-form McGill pain questionnaire was processed in the standard manner whereby the questionnaire is divided into a sensory and affective component. A score for each of these components is determined by calculating the sum of that component from the values of the words chosen by participants. A value of one point is given where the sensation or affect is described at being "mild", two points where this is described as "moderate" and three points where the description is "severe". The sum of the number of words chosen to describe the sensory and affective component was also calculated.

Data was statistically analyzed in a similar manner to data obtained from apparatus testing using the "Statgraphics plus" programme. The mean for the pain questionnaires and components thereof was calculated for each visit. This data is recorded in tables.

CHAPTER FOUR RESULTS

Results of data gathered from clinical testing and pain questionnaire responses are presented in table form.

Key to the tables:

CONS	consultation
CI	initial consultation
CF	final consultation
d	mean
SD	standard deviation
p	exceedence probability

4.1. GRIP STRENGTH TESTING RESULTS

Note: The "Collin" dynamometer used in this study to measure hand grip-strength is calibrated from zero to seventy. Each unit of calibration represents the force of one kilogram exerted on the apparatus. In this text this measurement is referred to as hand grip-strength units.

4.1.1. INTRA-GROUP COMPARISONS:

Table 1: Mean (d), standard deviation (SD) and exceedence probability (p) at initial (CI) and final consultation (CF) for placebo and treatment group left hand grip-strength measurements.

	PLACEBO			TREATMENT		
CONS.	**d**	**SD**	**p**	**d**	**SD**	**p**
CI	11.786	8.154	0.05	14.071	12.338	0.0117
CF	16.0	9.599		16.5	12.859	

A Wilcoxon signed rank test yielded a significant improvement ($p = 0.05$) in left hand grip strength for the placebo group. This correlates to an average increase of 4.214 grip strength meter units or 35.75% over the treatment period.

A statistically significant improvement ($p = 0.0117$) also occurred in the treatment group left hand grip strength correlating to an increase of 2.429 units or 17.26% over the treatment period.

Table 2: Mean (d), standard deviation (SD) and exceedence probability (p) at initial (CI) and final consultation (CF) for placebo and treatment group right hand grip-strength measurements.

CONS.	PLACEBO			TREATMENT		
	d	**SD**	**p**	**d**	**SD**	**p**
CI	16.667	6.510	0.1105	12.333	8.209	0.0117
CF	17.933	5.861		18.0	10.344	

A Wilcoxon signed rank test yielded no statistically significant change ($p = 0.1105$) in the placebo group right hand grip-strength over the treatment period.

Similar analysis of the treatment group right hand grip-strength yielded a statistically significant improvement ($p = 0.0117$) between the initial and final consultation. This correlates to an average increase of 5.667 grip-strength meter units or 45.95%. A dramatic increase in treatment group right hand grip- strength occurred between the third and fourth consultation of 3.786 grip-strength units (26.65%).

4.1.2. INTER-GROUP COMPARISONS:

Table 3: Mean (d), standard deviation (SD) and exceedence probability (p) at initial (CI) and final consultation (CF) for placebo and treatment group left and right hand grip-strength measurements.

	LEFT HAND			RIGHT HAND		
CONS.	**d**	**SD**	**p**	**d**	**SD**	**p**
CI	12.8667	10.2720	0.4633	12.8	7.6785	0.0723
CF	16.4667	11.5491	0.3478	16.3667	9.0972	0.3682

Mann-Whitney "U" testing yielded no statistically significant differences ($p = 0.4633$ and $p = 0.3478$) for the left hand grip-strength measurements between placebo and treatment groups at the initial and final consultations respectively. Similarly no statistical difference ($p = 0.0723$ and $p = 0.3682$) was found between placebo and treatment group right hand grip strength measurements at the initial and final consultations respectively. This is despite a difference of 4.334 grip strength meter units between the initial right hand placebo average of 16.667 units and the initial right hand treatment group average of 12.333 units.

At the final consultation the treatment group average of 18.0 grip strength units was marginally greater (0.067 units) than the placebo average of 17.933 units. The final left hand grip strength average is also similar with a placebo average of 16.0 units and treatment average of 16.5 units.

4.2. AFFECTED JOINT RANGE OF MOTION TESTING RESULTS:

Note: A small goniometer specific for hand and finger joint measurements was used in this study. The unit of measurement is degrees.

4.2.1. INTRA-GROUP COMPARISONS:

Table 4: Mean (d), standard deviation (SD) and exceedence probability (p) at initial (CI) and final consultation (CF) for placebo and treatment group left hand affected joint range of motion measurements.

CONS	PLACEBO			TREATMENT		
	d	**SD**	**p**	**d**	**SD**	**p**
CI	43.857	26.001	0.3125	49.549	17.370	0.0104
CF	43.863	24.374		51.646	16.161	

A Wilcoxon signed rank test yielded no statistically significant change ($p = 0.3125$) in placebo left hand affected joint range of motion over the treatment period.

Similar testing showed a statistically significant improvement ($p = 0.0104$) in the treatment group left hand affected joint range of motion. This correlates to an average increase over the treatment period of 2.097 degrees or 5.5%.

Table 5: Mean (d), standard deviation (SD) and exceedence probability (p) at initial (CI) and final consultation (CF) for placebo and treatment group right hand affected joint range of motion measurements.

CONS	PLACEBO			TREATMENT		
	d	**SD**	**p**	**d**	**SD**	**p**
CI	54.158	23.927	0.3918	45.189	13.179	0.0093
CF	54.187	21.188		49.057	14.623	

Wilcoxon signed rank testing showed no statistically significant change ($p = 0.3918$) in placebo group right hand affected joint range of motion between the initial and final consultations.

A statistically significant improvement ($p = 0.0093$) occurred in the treatment group right hand affected joint range of motion. This correlates to an increase of 3.868 degrees or 8.5% over the treatment period.

Marked increases occurred in both placebo and treatment group right hand affected joint range of motion measurements between visits three and four. This increase is more significant in the treatment group which showed an average increase of 4.706 degrees (10.6%) over visit three as opposed to the placebo group which showed an increase of 2.811 degrees (5.47%) over the same period. More importantly however, whereas the placebo increase brought the range of motion back to a similar level to that of the initial consultation, the treatment increase elevated the average affected joint range of motion by 3.868 degrees over the initial consultation.

4.2.2. INTER-GROUP COMPARISONS:

Table 6: Mean (d), standard deviation (SD) and exceedence probability (p) at initial (CI) and final consultation (CF) for placebo and treatment group left and right hand affected joint range of motion measurements.

	LEFT HAND			RIGHT HAND		
CONS	**d**	**SD**	**p**	**d**	**SD**	**p**
CI	43.0603	25.5572	0.201	45.2733	21.9690	0.2276
CF	44.1067	24.8709	0.2279	47.0103	21.0996	0.2807

Mann-Whitney "U" testing yielded no statistically significant differences ($p = 0.201$ and $p = 0.2279$) for the left hand and ($p = 0.2276$ and $p = 0.2807$) for the right hand affected joint range of motion measurements between placebo and treatment groups at the initial and final consultations respectively.

4.3. AESTHESIOMETER MEASUREMENT RESULTS:

Note: The gradation marks on the aesthesiometer used in this study have no particular unity and are merely a means of providing a more objective measurement (Luykx 1997). In this text these measurements are referred to as "aesthesiometer units".

4.3.1. INTRA-GROUP COMPARISONS:

Table 7: Mean (d), standard deviation (SD) and exceedence probability (p) at initial (CI) and final consultation (CF) for placebo and treatment group left hand aesthesiometer measurements.

	PLACEBO			TREATMENT		
CONS	**d**	**SD**	**p**	**d**	**SD**	**p**
CI	2.661	0.583	0.0263	4.431	1.579	0.1367
CF	2.941	0.724		4.514	1.658	

A Wilcoxon signed rank test yielded a statistically significant increase ($p = 0.0263$) in left hand aesthesiometer measurements of 0.28 units (10.5%) for the placebo group between initial and final consultations.

Similar analysis of the treatment group left hand aesthesiometer measurements yielded no statistically significant difference ($p = 0.1367$) over the treatment period.

Table 8: Mean (d), standard deviation (SD) and exceedence probability (p) at initial (CI) and final consultation (CF) for placebo and treatment group right hand aesthesiometer measurements.

CONS	PLACEBO			TREATMENT		
	d	**SD**	**p**	**d**	**SD**	**p**
CI	2.734	0.669	0.0223	3.868	1.614	0.0917
CF	3.118	0.983		4.112	1.752	

Wilcoxon signed rank testing yielded a statistically significant increase ($p = 0.0223$) in the placebo group right hand aesthesiometer measurements over the treatment period. This translates to an decrease in aesthesiometer sensitivity of 0.384 units (14%) between the initial and final consultations.

Similar analysis of the treatment group right hand aesthesiometer measurement data yielded no statistically significant changes ($p = 0.0917$) over the treatment period.

4.3.2. INTER-GROUP COMPARISONS:

Table 9: Mean (d), standard deviation (SD) and exceedence probability (p) at initial (CI) and final consultation (CF)for placebo and treatment group left and right hand aesthesiometer measurements.

	LEFT HAND			RIGHT HAND		
CONS	**d**	**SD**	**p**	**d**	**SD**	**p**
CI	12.8667	10.2720	0.0125	7.8098	7.6785	0.0189
CF	16.4667	11.5491	0.0394	16.3667	9.0792	0.0384

Mann-Whitney "U" testing yielded significant differences (p = 0.0125 and p = 0.0394) between placebo and treatment group left hand aesthesiometer measurements at the initial and final consultations respectively. Similar differences (p = 0.0189 and p = 0.0394) were found between placebo and treatment group right hand aesthesiometer measurements at the initial and final consultations respectively.

The average aesthesiometer measurement in the treatment group was 1.134 aesthesiometer units and 1.77 units higher at the initial consultation than the placebo average for the right and left hand respectively. Again this average was higher for the treatment group at the final consultation being 0.994 aesthesiometer units and 1.573 units higher for the right and left hand respectively. These higher aesthesiometer readings in the treatment group represent a lower pain sensitivity. Conversely, the lower sensitometer readings in the placebo group indicate a greater pain sensitivity.

4.4. AFFECTED JOINT CIRCUMFERENCE MEASUREMENT RESULTS:

Note: A "circumeter" (a small inertia reel tape-measure) was used in this study. The unit of measurement is centimetres.

4.4.1. INTRA-GROUP COMPARISONS:

Table 10: Mean (d), standard deviation (SD) and exceedence probability (p) at initial (CI) and final consultation (CF) for placebo and treatment group left hand affected joint circumference measurements.

CONS	PLACEBO			TREATMENT		
	d	**SD**	**p**	**d**	**SD**	**p**
CI	7.171	3.222	0.1205	6.620	2.356	0.2668
CF	7.147	3.348		6.690	2.418	

Wilcoxon signed rank testing yielded no statistically significant changes ($p = 0.1205$ and $p = 0.2668$) between the initial and final left hand joint circumference measurement data in the placebo and treatment groups respectively.

Table 11: Mean (d), standard deviation (SD) and exceedence probability (p) at initial (CI) and final consultation (CF) for placebo and treatment group right hand affected joint circumference measurements.

CONS	PLACEBO			TREATMENT		
	d	**SD**	**p**	**d**	**SD**	**p**
CI	6.262	1.580	0.0912	6.442	1.487	0.3918
CF	6.217	1.561		6.440	1.556	

Wilcoxon signed rank testing also yielded no statistically significant changes ($p = 0.0912$ and $p = 0.3918$) in right hand joint circumference measurement data between the placebo and treatment groups respectively.

4.4.2. INTER-GROUP COMPARISONS:

Table 12: Mean (d), standard deviation (SD) and exceedence probability (p) at initial (CI) and final consultation (CF)for placebo and treatment group left and right hand affected joint circumference measurements.

	LEFT HAND			RIGHT HAND		
CONS	**d**	**SD**	**p**	**d**	**SD**	**p**
CI	6.3108	3.3196	0.2052	5.9306	2.0615	0.4341
CF	6.2717	3.3581	0.3309	5.9155	2.0776	0.4917

Mann-Whitney "U" testing yielded no statistically significant differences (p = 0.2052 and p = 0.3309) for the left hand joint circumference measurements and (p = 4341 and p 0.4917) for the right hand joint circumference measurements between placebo and treatment groups at the initial and final consultations respectively.

4.5. 101-POINT NUMERICAL RATING SCALE RESULTS

4.5.1. INTRA-GROUP COMPARISONS:

Table 13: Mean (d), standard deviation (SD) and exceedence probability (p) at the initial (CI) and final consultations (CF) for placebo and treatment group NRS-101 scores.

CONS	TREATMENT			PLACEBO		
	d	**SD**	**p**	**d**	**SD**	**p**
CI	68.667	25.387	0.0072	65	23.679	0.1277
CF	44.667	35.328		56.333	28.251	

Wilcoxon signed rank testing yielded a statistically significant decrease ($p = 0.0072$) in scoring between the initial and final consultations for the treatment group NRS-101 score. This correlates to an average decrease of 24 points (34.95%) over the treatment period.

Similar analysis of the placebo group yielded no statistically significant change ($p = 0.1277$) in scores between the initial and final consultations for the NRS-101. The decrease of 8.7 points (13.3%) over the treatment period was not statistically significant.

A reduction in the NRS-101 score occurred at visit two in both the treatment and placebo group. The treatment group had a greater decrease of 19.667 points (28.6%) compared to the placebo decrease of 5.667 points (8.7%). At visit three the treatment group score

increased by 5.333 points (10.9%) as opposed to the placebo group where the score continued to decrease by 8 points (13.5%). The treatment group showed a significant decrease in score of 9.67 points (17.79%) at the final visit as opposed to the placebo group where an increase of 5 points (9.7%) was noted.

4.5.2. INTER-GROUP COMPARISONS:

Table 14: Mean (d), standard deviation (SD) and exceedence probability (p) at the initial (CI) and final consultation (CF) for the placebo and treatment group 101-point Numerical Rating Scale scores.

	101-POINT NUMERICAL RATING SCALE SCORES		
CONS	**d**	**SD**	**p**
CI	66.8333	23.7867	0.3686
CF	50.1667	31.3975	0.1391

Mann-Whitney "U" testing showed no statistically significant differences between the placebo and treatment groups in the 101-point NRS scores at either the initial or final consultations.

4.6. THE SHORT-FORM McGILL PAIN QUESTIONNAIRE SENSORY COMPONENT RESULTS:

4.6.1. INTRA-GROUP COMPARISONS:

Table 15: Mean (d), standard deviation (SD) and exceedence probability (p) at the initial (CI) and final consultation (CF) for placebo group McGill pain questionnaire sensory component scores.

CONS	SENSORY SCORE			NUMBER OF WORDS CHOSEN		
	d	**SD**	**p**	**d**	**SD**	**p**
CI	7.533	6.186	0.3532	3.533	2.099	0.3611
CF	7.667	6.997		3.667	2.225	

Wilcoxon signed rank testing yielded no statistically significant changes ($p = 0.3532$) for the sensory score and ($p = 0.3611$) for the number of words chosen to describe the sensory component between initial and final scores for the placebo group.

Table 16: Mean (d), standard deviation (SD) and exceedence probability (p) at initial (CI) and final consultation (CF) for treatment group McGill pain questionnaire sensory component scores.

CONS	SENSORY SCORE			NUMBER OF WORDS CHOSEN		
	d	**SD**	**p**	**d**	**SD**	**p**
CI	6	2.903	0.1165	3.067	1.624	0.2755
CF	4.8	3.590		2.8	1.521	

Analysis using the Wilcoxon signed rank test yielded no statistically significant differences ($p = 0.1165$) for the sensory score and ($p = 0.2755$) for the number of sensory words chosen between initial and final consultations.

4.6.2. INTER-GROUP COMPARISONS:

Table 17: Mean (d), standard deviation (SD) and exceedence probability (p) at initial (CI) and final consultation (CF)for placebo and treatment group sensory component scores of the McGill pain questionnaire.

	SENSORY SCORE			NUMBER OF WORDS CHOSEN		
CONS	**d**	**SD**	**p**	**d**	**SD**	**p**
CI	7.3667	4.6938	0.4667	3.6	1.8903	0.3289
CF	5.933	1.8903	0.0979	3.1667	1.8812	0.1640

Mann-Whitney "U" testing yielded no statistically significant differences ($p = 0.4667$ and $p = 0.0979$) for the sensory score and ($p = 0.3289$ and $p = 0.1640$) for the number of words chosen to describe the sensory component between placebo and treatment groups at the initial and final consultations respectively.

4.7. THE SHORT-FORM McGILL QUESTIONNAIRE AFFECTIVE COMPONENT RESULTS:

4.7.1. INTRA-GROUP COMPARISONS:

Table 18: Mean (d), standard deviation (SD) and exceedence probability (p) at initial (CI) and final consultation (CF) for placebo group McGill pain questionnaire affective component scores.

CONS	AFFECTIVE SCORE			NUMBER OF WORDS CHOSEN		
	d	**SD**	**p**	**d**	**SD**	**p**
CI	1.733	2.374	0.2419	0.8	0.9411	0.2877
CF	2.067	3.615		0.933	1.387	

Statistical analysis using the Wilcoxon signed rank test yielded no significant differences ($p = 0.2419$) for the affective score and ($p = 0.2877$) for the number of words chosen to describe the affective component for the placebo group between initial and final consultations.

The placebo group affective score remained constant between consultation one and three. At the final consultation however, the placebo affective score increased by 0.334 points (19%) over visits two and three.

Table 19: Mean (d), standard deviation (SD) and exceedence probability (p) at initial (CI) and final consultation (CF) for treatment group McGill pain questionnaire affective component scores.

CONS	AFFECTIVE SCORE			NUMBER OF WORDS CHOSEN		
	d	**SD**	**p**	**d**	**SD**	**p**
CI	0.667	1.291	0.1367	0.467	0.640	0.2113
CF	0.533	1.060		0.4	0.632	

Analysis using the Wilcoxon signed rank test yielded no statistically significant differences ($p = 0.1367$) for the affective score and ($p = 0.2113$) for the number of words chosen to describe the affective component for the treatment group between initial and final consultations. The treatment group affective score increased at visits two and three by 0.066 points (9.9%) and by 0.2 points (27.3%) respectively. At the final consultation however, this score had decreased by 0.466 points (49.95%) over visit three.

4.7.2. INTER-GROUP COMPARISONS:

Table 20: Mean (d), standard deviation (SD) and exceedence probability (p) at initial (CI) and final consultation (CF) for placebo and treatment group affective component scores of the McGill pain questionnaire.

	AFFECTIVE SCORE			NUMBER OF WORDS CHOSEN		
CONS	**d**	**SD**	**p**	**d**	**SD**	**p**
CI	1.433	1.9093	0.1103	0.8667	0.8055	0.1785
CF	1.133	2.6799	0.2065	0.5333	0.9911	0.2271

Mann-Whitney "U" testing yielded no statistically significant differences ($p = 0.1103$ and $p = 0.2065$) for the affective score and ($p = 0.1785$ and $p = 0.2271$) for the number of words chosen to describe the affective component between placebo and treatment groups at the initial and final consultations respectively.

CHAPTER FIVE DISCUSSION

5.1. TESTING WITH CLINICAL APPARATUS

5.1.1. HAND GRIP STRENGTH TESTING

Factors associated with osteoarthritis of the hand which might affect grip-strength include pain, stiffness, muscle wasting and reduced mobility due to bone remodelling. Testing for grip-strength can therefore give important information on how homoeopathic treatment affects these factors.

Over the treatment period, an average increase in left hand grip-strength of 4.214 units (35.75%) and 2.429 units (17.26%) was noted in the placebo and treatment groups respectively. The treatment group right hand showed an increase of 5.667 grip-strength meter units (45.95%) over the same period. A minor increase of 1.256 units occurred in the placebo group right hand.

Unsworth et al. (1990) found that right hand grip strength is greater than left hand strength. This was found to be true at the end of the research period. However the treatment group right hand grip strength was weaker (12.333 units) than the left hand (14.071 units) at the start of the study.

Only very minor changes were noted in circumference measurement and no changes were observed on x-ray follow up. The improvement

in grip-strength over the study period is therefore more likely due to an improvement in pain perception rather than any other factors. This is supported by improved 101-point Numerical Rating Scale scores indicating reduced pain intensity.

A fear of pain was observed by the researcher as being a factor affecting grip-strength. Some participants expressed concern that squeezing the grip-strength device would cause them pain. It may be that participants who had comparatively very low grip-strengths of one or two grip-strength units were to some extent affected by a fear of pain when asked to grip the device as hard as they could. An example is shown in the treatment group at the initial consultation where two participants had a grip-strength of one unit and one participant had a strength of two units compared to the group average of 12.333 units. These low grip-strength's found in the treatment group negatively impacted on the group average.

Nordenskiold and Grimby (1993) criticise the use of air filled bags and spring devises for measuring grip-strength on the basis that difficulties in replicating grip position and in calibrating spring devises affect the reproducibility of these measurements. Furthermore these authors points out that the commonly used grip force relates to the maximum grip at a certain moment in time. This therefore does not give information about the ability of muscles to sustain their contraction and is also dependant on patient motivation to grip to their maximum capabilities at that moment.

This author agrees that subjective influences including motivation and a fear of pain affect grip-strength device measurements. Nordenskiold and Grimby (1993) discuss the development of an electrical device which measures sustained grip-strength thereby giving better information on muscle strength. In the absence of such a device it is suggested that continued use be made of a calibrated spring device due to the simple design which could fit easily and comfortably into the palms of all participants hands.

5.1.2. JOINT RANGE OF MOTION TESTING

The range of motion of osteoarthritic hand joints is likely to be affected by pain, muscle spasm and bony remodelling including osteophyte formation and capsular fibrosis. Range of motion testing is therefore another method of assessing the impact homoeopathic treatment has on osteoarthritis.

Treatment patients showed an average increase in joint range of motion over the treatment period of 3.868 degrees (8.5%, $p = 0.0093$) for right hand joints and 2.097 degrees (5.5%, $p = 0.0104$) for left hand joints. Insignificant changes occurred in the placebo group.

The increases in range of motion indicate minimal clinical significance, averaging out at an increase of 0.77 degrees for treatment patient right hand individually affected joints and

0.42 degrees for left hand affected joints. These increases are important, however, when compared to placebo patients where joint range of motion remained largely static.

Again it can be argued that an improvement in pain perception is largely responsible for the increases in joint range of motion. The absence of any observable changes on follow up x-ray's indicates an unlikelihood of any improvement having occurred in bone structure.

As with grip-strength measurements, motivation and pain perception are considered by this researcher to be subjective influences affecting hand-joint range of motion measurements. These tests are dependant on the ability of participants to move their joints into position for measurement. A fear of inducing pain by the clenched finger positions used to assess mobility may affect results. This opinion would support the finding of improved range of motion measurements related to an improved pain perception over the study period.

Motivation has been mentioned as a possible subjective factor affecting grip-strength and range of motion measurements. In the clinical setting of this research however, where patients were encouraged to grip the measuring device as hard as they could and to clench their fingers together as tightly as they could, it is considered that motivation was well maintained.

5.1.3. SKIN SENSITIVITY TESTING

Articular cartilage which is primarily affected by osteo-arthritis is devoid of nerves (Harkness et al. 1985:217). The cause of osteoarthritic pain therefore remains obscure. The pain sensitivity of skin overlying osteoarthritic joints is used therefore to provide an articular index of joint sensitivity (Fisher 1990:35).

Statistically significant inter-group differences (initial left hand $p = 0.0125$ and final $p = 0.0394$ and initial right hand $p = 0.0189$ and final $p = 0.0394$) emerged from Mann-Whitney "U" comparisons between the placebo and treatment group at both the initial and final consultation.

Appendix 1 shows that in the placebo group the highest initial aesthesiometer reading was 3.75 units (left hand) and two participants had an aesthesiometer reading of four units (right hand). In the treatment group, appendix 2 shows that six participants had an initial aesthesiometer reading of four units or more (right hand) and seven participants had a reading of four units or more (left hand). This represents an unfortunate distribution of participants on a double-blind basis. This researcher suggests larger study groups to minimalise the effects different patient skin sensitivities have on group averages.

Only the placebo group showed a statistically significant

decrease in skin sensitivity over the treatment period: left hand p = 0.0263, indicating an improvement of 0.28 units (10.5%), and right hand p = 0.0223, an improvement of 0.384 units (14%). The corresponding improvement in treatment patients was minimal.

The improvement in skin sensitivity in the placebo group is probably due to the placebo effect. Richardson (1989:36) claims that symptomatic relief can be achieved through the placebo effect in almost all disorders. Tedeschi et al. (1971) cited in Richardson (1989:43) find that reporting error associated with placebo treatment feedback occurs when patients, in an attempt to please the researcher, report altered symptoms, or where the therapist observer in a placebo trial, in a wish or expectation to observe therapeutic effects may have a biased perception or recording of data obtained.

It is suggested that the greater skin sensitivity encountered in the placebo group may have allowed for a larger scope of improvement due to clinical intervention.

5.1.4. JOINT CIRCUMFERENCE MEASUREMENT TESTING

Several factors associated with osteoarthritis contribute to joint enlargement. Heberdens nodes, which occur predominantly in middle aged women, are gelatinous cysts or bony outgrowths found

on the dorsal aspects of the distal interphalangeal joints (Edwards and Bouchier 1991:800). Mannik and Gilliland (1974:2006) state that one quarter of patients who have Heberdens nodes, have similar nodosities on the proximal interphalangeal joints called Bouchards nodes. Capsular fibrosis, joint effusions, and occasional inflammation (Edwards and Bouchier 1991:799) are other features of osteoarthritis which may contribute to joint enlargement.

Joint circumference measurements remained largely static throughout the study period. Statistical analysis of joint circumference measurement testing yielded no significant changes.

Apart from occasional inflammation surrounding osteoarthritic joints, which tends to be acute and transitory (Edwards and Bouchier 1991:799) and which could therefore affect joint circumference measurements, it may be that the bony remodelling associated with osteoarthritis represents a permanent change in joint circumference. It is therefore probable that the only intervention likely to affect joint circumference is surgery.

Inflammation of the hand joints was not found in this study to be a significant factor affecting joint circumference.

5.2. RESULTS OF X-RAY EXAMINATIONS

X-ray examination of the hands and wrists was used to diagnose osteoarthritis (Buckland-Wright 1994) and to monitor disease modification (Dieppe et al. 1995).

No changes in radiographic features were detected in any of the follow up x-rays indicating that no radiologically measurable changes had occurred over the trial period.

Buckland-Wright (1994) observed changes in the distribution, extent and progression of x-ray features over an 18 month study period. Hochberg (1996) found that progression of radiographic features of osteoarthritis and in particular osteophyte formation, could be observed in two and five year follow ups of the disease. In this research the three month study period was probably insufficient to observe changes in the radiological features of osteoarthritis. It is also recommended that a retrospective comparative study be conducted to determine if homoeopathic treatment slows down the progression of radiographic features of osteoarthritis.

The use of x-ray's in osteoarthritis studies have come under recent criticism. Buckland-Wright (1994) finds that radiographic scoring systems are an essential and widely used method of describing disease progression but that they suffer from several drawbacks: They are based on two assumptions, firstly that the change in any one x-ray feature is linear and constant during

the course of the disease and secondly that the relationship between the different x-ray features is constant. This means that scoring radiographs do not account for the possibility that different radiographic features may progress at different rates and at different times. Buckland-Wright (1994) suggests that a far better knowledge of the natural history and outcome of the disease is required so that the relative significance of the different radiographic features can be better understood.

Hart et al. (1994) note that radiographic scoring of osteoarthritis including the system devised by Kellgren and Lawrence (1957) is currently undergoing reassessment. Inconsistent descriptions of the grading criteria, uncertain reproducibility of grades and overemphasis on isolated osteophyte formation are cited by Hart et al. (1994) as factors whose relative importance in grading osteoarthritis severity are being reappraised.

5.3. PAIN PERCEPTION QUESTIONNAIRE ANALYSIS

Pain is cited by Moskowitz (1993:1739) as being the cardinal symptom of osteoarthritis. Any improvements in pain perception can therefore be regarded as beneficial therapeutic properties of homoeopathic treatment.

5.3.1. 101-POINT NUMERICAL RATING SCALE RESULTS

The most common methods of rating perceived pain intensity utilise rating scales such as the Numerical Rating Scale (Richardson 1989).

Statistically significant improvements were found in the treatment group 101-point Numerical Rating Scale responses ($p = 0.0072$). This correlates to an average decrease of 24 points (34.95%) over the treatment period. The corresponding decrease for the placebo group was 8.7 points (13.3%) which was not found to be statistically significant.

5.3.2. McGILL PAIN QUESTIONNAIRE RESULTS

The McGill pain questionnaire responses were analyzed in two components, the pain sensory component and the pain affective component. A corresponding analysis of the number of words chosen for each component was included.

5.3.2.1. SENSORY COMPONENT:

No statistically significant changes occurred in the scoring of the sensory component or the average number of words chosen to describe the sensory component in either the intra-group or inter-group analyses. The largest change between the initial and final sensory scores occurred in the treatment group with an average decrease of 1.2 points.

The treatment group had a consistently lower sensory component score at all visits. Tables 15 and 16 show that the treatment group had an initial sensory score 1.533 points lower than the placebo group and appendices nine and ten indicate an average sensory score 1.956 points lower than the placebo group at visits two, three and four. This ties in with data obtained from aesthesiometer measurements where the treatment group had a consistently higher pain threshold compared to the placebo group.

Although Mann-Whitney "U" testing did not indicate statistically significant inter-group differences at the initial and final consultations as was shown in aesthesiometer results, it is suggested that a larger study group would give a more similar distribution of sensory scores. More accurate comparisons between treatment and placebo effects could then be made.

5.3.2.2. **AFFECTIVE COMPONENT**

Analysis of the affective component of the McGill pain questionnaire yielded no statistically significant changes between intra-group or inter-group data.

Tables 18 and 19 show a higher placebo score of 1.066 affective points at the initial consultation and 1.6 points at the final consultation when compared to treatment group data. As in the sensory component data, Mann-Whitney "U" comparisons did not indicate statistically significant inter-group differences

between the treatment and placebo groups at these consultations.

Despite this evidence indicating no statistically significant differences between the treatment and placebo groups, it is again the researcher's opinion that these differences are clinically large enough to affect accurate comparisons.

5.4. SUGGESTIONS FOR FUTURE RESEARCH

The following suggestions are made to increase the reliability and applicability of future research.

In a disease which can last a lifetime, March and Brooks (1996) suggest that studies of short duration (three months) are probably inappropriate for even rapidly acting symptom controlling drugs including non-steroidal anti-inflammatory drugs and analgesics. Retrospective studies over a period of at least eighteen months would provide more accurate information on how homoeopathic treatment can affect the course of osteoarthritis.

The use of larger study groups is recommended so that more accurate comparisons between placebo and treatment results can be made. Larger study groups would also enhance the reliability and applicability of this research.

Although pain is cited as being a cardinal symptom of

osteoarthritis, several participants in this trial claimed to have no pain or only very minor pain related to their hand osteoarthritis. Bellamy (1995) states that two purpose built instruments for use in osteoarthritis research have recently emerged. These are the Western Ontario and McMaster Universities osteoarthritis index (WOMAC) and the Lequesne Index. This researcher recommends that further research into homoeopathic treatment of osteoarthritis consider the use of these instruments in light of Bellamy's suggestion that these tests need further investigation to determine their efficacy and reliability.

Richardson (1989:38) states that the popular stereotype of placebo administration is the sugar coated pill and that variations in placebo effectiveness can be attributed to their physical appearance. In this trial the common homoeopathic white sugar based pillules were used and although treatment and placebo pillules were identical in taste and appearance, two participants expressed the opinion that they must be placebo patients because they were getting little white sugar pills. This researcher therefore recommends that another form of medicine administration be used.

In light of growing criticism of the use of radiographic imaging for the evaluation of osteoarthritis progression, this researcher recommends that further research into the homoeopathic treatment of osteoarthritis be preceded by a preliminary study into the use and reliability of a wide range

of emerging imaging techniques. March and Brooks (1996) state that the study of cartilage structure has greatly improved with the advent of magnetic resonance imaging (M.R.I.) and that developments in this technique will improve the poor resolution and tissue discrimination capabilities currently associated with the use of this technique in bone and cartilage studies. George and Dieppe (1994) describe several modern imaging techniques which can be used in the study of osteoarthritis including scintigraphy which can detect the activity of the marginal and subchondral bone and magnetic resonance imaging (M.R.I.) which can detect early changes in soft tissues as well as bone. Computerised tomography is also recommended as an imaging technique which may show abnormalities earlier than radiographs.

CHAPTER SIX: CONCLUSIONS AND RECOMMENDATIONS

Improvements in hand grip-strength and joint range of motion and in pain intensity measured by the 101-point Numerical Rating Scale are shown in this investigation. This demonstrates that homoeopathic treatment positively affects both functional and subjective aspects of osteoarthritis.

With consideration to the opinion that pain is the cardinal symptom of osteoarthritis and in light of the serious and occasionally fatal side effects of allopathic non-steroidal anti-inflammatory drugs commonly used to control this pain, the improvement in perceived pain intensity evidenced by the improvement in the 101-point Numerical rating scale scores suggests that further research should be conducted into the homoeopathic control of osteoarthritic pain.

A growing interest into the osteoarthritic condition is evidenced by increasing research into all aspects of the condition over the last decade. A recommendation is that further research into the homoeopathic treatment of osteoarthritis be preceded by thorough investigation of the most recent developments. Future research can then pinpoint more specific areas where homoeopathic treatment may affect the osteoarthritic condition and in so doing expand on the findings of this project.

REFERENCES

Ahern, M.J., McFarlane, A., Leslie, A., Eden, J and Roberts-Thomson P.J. 1995. Illness behaviour in patients with arthritis. Annals of the Rheumatic Diseases, 54:245-250.

Altman, R.D. 1995. The classification of osteoarthritis. The Journal of Rheumatology, (supplement 43) 22(1):42-43.

Badley, E.M. 1995. The effect of osteoarthritis on disability and health care use in Canada. The Journal of Rheumatology, (supplement 43) 22(1):19-22.

Basmajian, J.V. and Nyberg, R. 1993. Rational Manual Therapies. Baltimore: Williams and Wilkens. 484 p. ISBN 0-683-00420.

Bellamy, N. 1995. Outcome measures in osteoarthritis clinical trials. The Journal of Rheumatology, (supplement 43) 22(1):49-51.

Blower, A.L. 1996. Considerations for non-steroidal anti-inflammatory drug therapy: Safety. Scandinavian Journal of Rheumatology, (supplement 105) 25:13-26.

Boyer, R. 1994. Treatment of Arthritic Conditions. Unpublished Lecture Notes. Technikon Natal, Durban, Department of Homoeopathy.

Buckland-Wright, J. 1994. Quantitative radiography of osteoarthritis. Annals of the Rheumatic Diseases, 53:268-275.

Buckwalter, J.A. 1995. Osteoarthritis and articular cartilage use, disuse and abuse: Experimental studies. The Journal of Rheumatology, (supplement 43) 22(1):13-15.

Burckhardt, C.S. and Bjelle, A. 1994. A Swedish Version of the Short-Form McGill Pain Questionnaire. Scandinavian Journal of Rheumatology, 23(1):77-81.

Cauley, J.A., Kwoh, C.K., Egeland, G., Nevitt, M.C., Cooperstein, L., Rohay, J., Towers. and Gutai, J.P. 1993. Serum sex hormones and severity in osteoarthritis of the hand. The Journal of Rheumatology, 20(7):1170-1173.

Cicuttini, F.M. and Spector, T.D. 1996. Genetics of osteoarthritis. Annals of the Rheumatic Diseases, 55:665-676.

Cooper, C. 1995. Occupational activity and the risk of osteoarthritis. The Journal of Rheumatology, (supplement 43) 22(1):10-12.

Croft, P. 1990. Osteoarthritis. British Journal of Rheumatology, 29:391-395.

David, M.J., Vignon, E., Peschard, M.J., Broquet, P., Louisot, P. and Richard, M. 1992. Effect of non-steroidal anti-inflammatory drugs on glycosyltransferase activity from human osteoarthritic cartilage. British Journal of Rheumatology, (supplement 1) 31:13-17.

de Koning, M. 1997. Faxed letter to author, 24 January 1997 (11:10 a.m.).

Dieppe, P. 1995. Therapeutic targets in osteoarthritis. The Journal of Rheumatology, (supplement 43) 22(1):136-139.

Dieppe, P., Brandt, K.D., Lohmander, S. and Felson, D.T. 1995. Detecting and measuring disease modification in osteoarthritis. The need for standardised methodology. The Journal of Rheumatology, (supplement 43) 22(1): 201-203.

Doube, A. and Morris, A. 1988. Non-steroidal induced dyspepsia. British Journal of Rheumatology, 27:110-112.

Edwards, C.R.W. and Bouchier, I.A.D. 1991. Davidson's principles and practise of medicine. Sixteenth edition. Edinburgh: Churchill Livingstone. 1032p. ISBN 0-443-04092-3.

Emery, P. 1996. Considerations for non-steroidal anti-inflammatory drug therapy: Benefits. Scandinavian Journal of Rheumatology, (supplement 105) 25:5-12.

Felson, D.T. 1995. Weight and osteoarthritis. The Journal of Rheumatology, (supplement 43) 22(1):7-9.

Fisher, P. 1990. Research into homoeopathic treatment of rheumatological disease: why and how? Complimentary Medical Research, 4(3):34-40. ISSN 0268-4055.

Fraser, P. 1993. Introduction to Homoeopathy. Unpublished Lecture Notes. Technikon Natal, Durban, Department of Homoeopathy.

Gabriel, S.E., Crowson, C.S. and O'Fallon, W.M. 1995. Costs of osteoarthritis: Estimates from a geographically defined population. The Journal of Rheumatology, (supplement 43) 22(1):23-25.

George, E. and Dieppe, P.A. 1994. Osteoarthritis. Update, IX:213-223.

Gilliland, B.C. and Mannik, M. 1974. Rheumatoid arthritis. In Wintrobe, M.M., Thorn, G.W., Adams, R.D., Braunwald, E., Isselbacher, K.J. and Petersdorf, R.G. Harrisons Principles of Internal Medicine. Seventh Edition. Pages 1987-1995. Kogakusha (Tokyo): McGraw-Hill. 2044 p. ISBN 0-07-071134-8.

Hardingham, T.E., Bayliss, M.T., Rayan, V and Noble, D.P. 1992. Effects of growth factors and cytokines on proteoglycan turnover in articular cartilage. British Journal of Rheumatology, (supplement 1) 31:1-6.

Harkness, J.A.L., Higgs, E.R. and Dieppe, P.A. 1985. Osteoarthritis. In Wall, P.D. and Melzack, R. Textbook of Pain. 215-224. Edinburgh: Churchill Livingstone (Longman). 866 p. ISBN 0-443-02715-3.

Hart, D., Spector, T., Egger, P., Coggon, D. and Cooper, C. 1994. Defining osteoarthritis of the hand for epidemiological studies: The Chingford study. Annals of the Rheumatic Diseases, 53:220-223.

Hindshaw, M., Bossert, L. and Els, P. 1985. Arthritis. Group Project. Technikon Natal, Durban.

Hochberg, M.C. 1996. Prognosis of osteoarthritis. Annals of the Rheumatic Diseases, 55:685-688.

Hochberg, M.C., Kasper, J., Williamson, J., Skinner, A. and Fried, L.P. 1995. The contribution of osteoarthritis to disability: Preliminary data from the Women's health and aging study. The Journal of Rheumatology, (supplement 43) 22(1):16-17.

Hochberg, M.C. 1996. Development and progression of osteoarthritis. The Journal of Rheumatology, 23:1497-1498.

Hutton, C.W. and Vennart, V. 1995. Osteoarthritis and magnetic resonance imaging: potential and problems. Annals of the Rheumatic Diseases, 54:237-243.

Hutton, C. 1994. Osteoarthritis revisited and revived. Annals of the Rheumatic Diseases, 53:85-86.

Jacobsson, L.T.H. 1996. Definitions of osteoarthritis in the knee and hand. Annals of the Rheumatic Diseases, 55:656-657.

Jensen, M.P., Karoly, P. and Braver, S. 1986. The measurement of clinical pain intensity: a Comparison of six methods. Pain, 27:117-126.

Khoker, M.A. and Dandona, P. 1988. The effect of Indomethacin and Aspirin on alkaline phosphatase secretion and thymidine incorporation by human osteoblasts. British Journal of Rheumatology, 27:291-294.

Lane, N.E. 1995. Exercise: a cause of osteoarthritis. The Journal of Rheumatology, (supplement 43) 22(1):3-6.

Large, R.G., 1996. Psychological aspects of pain. Annals of the Rheumatic Diseases, 55:340-345.

Lockie, A. and Geddes, N. 1995. The Complete Guide to Homoeopathy, the Principles and Practise of Treatment. London: Dorling Kindersley Limited. 240p. ISBN 0-7513-0209-0.

Luykx, R. 1997. Faxed letter to author, 24 January 1997 (11:10 a.m.).

Mannik, M. and Gilliland, B.C. 1974. Degenerative joint disease. In Wintrobe, M.M., Thorn, G.W., Adams, R.D., Braunwald, E., Isselbacher, K.J. and Petersdorf, R.G. Harrisons Principles of Internal Medicine. Seventh Edition. Pages 2005-2011. Kogakusha (Tokyo): McGraw-Hill. 2044p. ISBN 0-07-071134-8.

March, L.M. and Brooks, P.M. 1996. Clinical trials in osteoarthritis. Annals of the Rheumatic Diseases, 55:491-493.

McCarty, D.J. and Koopman, W.J. 1993. Arthritis and Allied Conditions - a Textbook of Rheumatology. Twelfth edition. Pennsylvania. Lee and Febiger. Volume 1 (1149 p.) and Volume 2 (950 p.). ISBN 0-8121-1430-2.

Melzack, R. 1987. The short-form McGill Pain Questionnaire. Pain, 30:191-197.

Moskowitz, R.W. 1993. Clinical and laboratory findings in osteoarthritis. In McCarty, D.J. and Koopman, W.J. Arthritis and Allied Conditions, a Textbook of Rheumatology. Twelfth edition. Pennsylvania: Lee and Febiger. Volume 1 (1149 p.) and Volume 2 (950 p.). ISBN 0-8121-1430.

Nordenskiold, U.M. and Grimby, G. 1993. Grip force in patients with rheumatoid arthritis and fibromyalgia and in healthy subjects. A study with the Grippit instrument. Scandinavian Journal of Rheumatology, 22:14-19.

O'Driscoll, S.L. and Jayson, M.I.V. 1982. The clinical significance of pain threshold measurement. Rheumatology and Rehabilitation , 21:31-35.

Richardson, P. 1989. Placebos: their effectiveness and modes of action. In Broome, A. Health Psychology and Processes of Application. New York: Chapman and Hall. 498 p. ISBN 0412-33200-0 (Hb).

Shipley, M., Berry, H., Broster, J., Jenkins, M., Clover, A. and Williams, I. 1983. Controlled Trial of Homoeopathic treatment of osteoarthritis. The Lancet, January 1983:97-98.

Spector, T.D. and Hochberg, M.C. 1994. Methodological problems in the epidemiological study of osteoarthritis. Annals of the Rheumatic Diseases, 53:143-146.

Taylor, J., Krondl, M. and Rao, V. 1989. Acetylsalicylic acid dose fails to affect energy intake of osteoarthritic elderly. Journal of Nutrition of the Elderly, 8:3-4.

Turk, D.C. and Melzack, R. 1992. Handbook of Pain Assessment. New York: The Guilford press. 491 p. ISBN 0-89862-883-0.

Unsworth, A., Haslock, I., Vasandakumar, V. and Stamp, J. 1990. A Laboratory and clinical study of 'Pneumatic grip strength' devices. British Journal of Rheumatology, 29:440-444.

Wall, P.D. and Melzack, R. 1985. Textbook of Pain. London: Churchill Livingstone Publishers. 664 p. ISBN 0-443-02715-3

APPENDICES

APPENDIX A

The data in this table relates to the hand grip-strength measurements for the right hand (R) and left hand (L) of the control group from consultation one (GSR1, GSL1) through four (GSR4, GSL4). The unit of measurement is the kilogram.

PLACEBO GROUP HAND GRIP STRENGTH								
NO	GSR1	GSR2	GSR3	GSR4	GSL1	GSL2	GSL3	GSL4
1	14	12	17	20	10	14	17	17
2	8	10	7	7	7	6	7	7
3	10	14	14	24	2	11	9	27
4	17	19	21	20	5	14	14	15
5	10	10	10	11	3	5	2	3
6	0	0	0	0	25	24	26	23
7	20	14	16	21	15	14	13	14
8	22	14	12	13	9	11	10	2
9	21	20	21	23	10	8	10	16
10	15	16	20	19	16	17	16	16
11	25	25	23	25	29	29	29	36
12	7	9	9	8	5	6	6	6
13	27	20	22	19	0	0	0	0
14	12	10	12	14	13	14	16	20
15	17	21	22	22	14	26	22	26

APPENDIX B

The data in this table relates to the hand grip-strength measurements for the right hand (R) and left hand (L) of the treatment group from consultation one (GSR1, GSL1) through four (GSR4, GSL4). The unit of measurement is the kilogram.

TREATMENT GROUP HAND GRIP STRENGTH								
NO	GSR1	GSR2	GSR3	GSR4	GSL1	GSL2	GSL3	GSL4
1	12	20	21	22	12	12	14	15
2	10	14	11	12	9	11	8	9
3	12	14	17	24	11	13	15	11
4	16	23	26	25	32	22	20	26
5	22	24	24	32	43	49	49	51
6	12	15	16	22	12	10	12	15
7	0	0	0	0	26	31	34	35
8	2	5	6	5	2	4	5	4
9	1	3	4	9	3	7	7	10
10	13	10	15	15	13	13	14	14
11	1	2	1	1	2	2	2	2
12	6	7	5	2	5	6	5	7
13	7	9	9	20	9	14	17	17
14	24	22	23	24	30	32	33	33
15	21	20	21	22	14	10	14	17

APPENDIX C

The data in this table relates to the average joint range of motion for the right hand (R) and left hand (L) of the control group from consultation one (RMR1, RML1) through four (RMR4, RML4). The unit of measurement is degrees.

PLACEBO GROUP AVERAGE RANGE OF MOTION								
NO	RMR1	RMR2	RMR3	RMR4	RML1	RML2	RML3	RML4
1	38.67	37.67	36	38	35	28	29.5	30
2	37.5	37	38	37.5	40	41.5	41	41
3	52	54.3	57.67	63.67	63.3	63.33	63.7	71.6
4	88	77	83	83.5	89	71	78	76
5	47	51.3	48.67	49.67	46.67	48	48.67	47
6	0	0	0	0	80	78	79	79
7	19.67	19.67	19.67	20	23	23	23	24
8	58	59	63	61	3	3	3	3
9	90	80	80	86	87	79	78.5	82
10	15.33	15.67	20	22.67	18	17.5	18	18.5
11	70.75	68.5	64.5	67	63.25	61.75	57.5	60
12	46	47	46	46	40.5	42	41	42
13	84.75	80.75	77.25	73.5	9.75	11.25	12.5	13.2
14	48.5	48.5	49.5	48.5	53	55.33	59	62.3
15	36.2	38.6	36	36.8	42.5	42.5	45.5	43

APPENDIX D

The data in this table relates to the average joint range of motion for the right hand (R) and left hand (L) of the treatment group from consultation one (RMR1, RML1) through four (RMR4, RML4). The unit of measurement is degrees.

TREATMENT GROUP AVERAGE RANGE OF MOVEMENT								
NO	RMR1	RMR2	RMR3	RMR4	RML1	RML2	RML3	RML4
1	22	21.33	21.67	22	20	21.67	22.66	23.6
2	61	60.5	62	62	83	82	82.5	82.5
3	72	72	74.5	68	75.5	76.5	73.5	75.8
4	41.33	40.67	41.33	41.33	60	60.5	62	61.5
5	55	55.2	55.6	55.4	41	43	45	45
6	51	53.33	57	62	47.5	47.5	48	48
7	0	0	0	0	52	58	51.05	59.8
8	42	42.2	43	42.6	0	0	0	0
9	29.5	31.5	32	39.75	34.67	38	35.33	41.7
10	26.25	30	28.5	30.25	37.67	37	38.67	40
11	38	38.33	37.67	38.67	41	39	41.33	40.7
12	41	41	40	43	0	0	0	0
13	51	77	76	76	50.5	57	56	57
14	48.75	47.5	49.5	49	0	0	0	0
15	47	47	46.5	46.5	55	50	54	55

APPENDIX E

The data in this table relates to the average "Aesthesiometer" readings for the right hand (RH) and left hand (LH) of the control group from consultation one (SS1) through four (SS4). The measurements have no particular unity (Luykx 1997) and are referred to as "aesthesiometer units".

PLACEBO GROUP AESTHESIOMETER READINGS								
NO	RHSS1	RHSS2	RHSS3	RHSS4	LHSS1	LHSS2	LHSS3	LHS4
1	2.67	2.67	2.67	2.67	3	2	2.5	2.5
2	2	2	2	2	2	2	2	2
3	2.67	2.67	2.67	3.33	3.33	3.33	4	4
4	2	2.5	2.5	2.5	2	3	2	3
5	2.67	2.67	2.67	2.67	2.67	2.67	2.67	2.67
6	0	0	0	0	2	5	6	6
7	3	3	2.67	3	3	2.5	2.75	2.5
8	3	2.5	3	3	3	3	4	4
9	3	4	3	3	3	3.5	3.5	3.5
10	3	3	3	3	3	3.5	4	4
11	4	4	3.75	4	3.75	3.5	3.25	3.5
12	3	2.5	2.5	3	2.5	2	2.5	2.5
13	2	2	2	2	2	2	2	2
14	4	3.5	4	4	2	2.33	2.67	2.5
15	2	2	2.4	2.6	2	2.5	3	2.5

APPENDIX F

The data in this table relates to the average "Aesthesiometer" readings for the right hand (RH) and left hand (LH) of the treatment group from consultation one (SS1) through four (SS4). The measurements have no particular unity (Luykx 1997) and are referred to as "aesthesiometer units".

TREATMENT GROUP AESTHESIOMETER READINGS								
NO	RHSS1	RHSS2	RHSS3	RHSS4	LHSS1	LHSS2	LHSS3	LHS4
1	3	3	3.33	3.33	4.33	4	4.33	4.33
2	2.5	2	2.5	2.5	2.5	2.5	2.5	2.5
3	2.25	3.25	3.25	3.5	3.5	4	4	4
4	4.33	3.67	4	4	4.5	4.5	4	4.5
5	7	7	7	7	7	7	7	7
6	2.33	2.67	3	3	5	4.5	5	5
7	2.75	2.5	2.5	2	0	0	0	0
8	3.6	3.6	3.4	3.6	0	0	0	0
9	5	4.75	5	4.75	5	6	4.33	5.64
10	4.75	5	4.5	5.5	5.33	5.67	5	5.67
11	2	2	2	2	2	2	2	2
12	5	5	4	7	0	0	0	0
13	3	3	2.5	3	3	2	2.5	2.5
14	7	7	7	7	0	0	0	0
15	3.5	3.5	3	3.5	4	4	4	4

APPENDIX G

The data in this table relates to the average joint circumference measurements for the right hand (R) and left hand (L) of the control group from consultation one (CMR1, CML1) through four (CMR4, CML4). The unit of measurement is the centimetre.

PLACEBO GROUP AVERAGE CIRCUMFERENCE MEASUREMENT								
NO	CMR1	CMR2	CMR3	CMR4	CML1	CML2	CML3	CML4
1	5.367	5.53	5.467	5.433	5.55	5.55	5.55	5.4
2	5.7	5.65	5.6	5.65	5.65	5.55	5.65	5.6
3	8.2	8.167	8.167	7.967	8	7.93	7.97	8
4	6.35	6.2	6.05	6.15	6.8	6.8	6.8	6.8
5	9.567	9.53	9.63	9.567	9.2	9.167	9.167	9.2
6	0	0	0	0	8.9	8.8	8.9	8.9
7	4.967	4.867	5	4.9	4.975	4.975	4.9	4.93
8	6.25	6.45	6.3	6.15	17.6	18	18	18
9	6.9	7	6.9	6.8	6.3	6.15	6.1	6.1
10	5.67	5.53	5.53	5.4	5.95	5.9	5.8	5.75
11	6.25	6.35	6.475	6.4	6.35	6.35	6.45	6.28
12	5.6	5.75	5.7	5.6	5.45	5.5	5.5	5.45
13	4.85	4.9	4.9	4.9	5.975	6.025	5.975	6.03
14	5.8	5.75	5.95	5.9	5.733	5.7	5.67	5.6
15	6.2	6.18	6.475	6.22	6.5	6.45	6.75	6.5

APPENDIX H

The data in this table relates to the average joint circumference measurements for the right hand (R) and left hand (L) of the treatment group from consultation one (CMR1, CML1) through four (CMR4, CML4). The unit of measurement is the centimetre.

TREATMENT GROUP AVERAGE CIRCUMFERENCE MEASUREMENT								
NO	CMR1	CMR2	CMR3	CMR4	CML1	CML2	CML3	CML4
1	4.767	4.866	4.8	4.767	5.4	5.3	5.33	5.33
2	6.9	6.925	6.9	6.925	5.675	5.6	5.625	5.65
3	6.1	5.975	5.925	5.9	5.825	5.675	5.625	5.65
4	10.87	11.33	11.17	11.07	12.95	13.05	12.85	12.9
5	7.08	7.14	7.1	7.14	9.8	9.8	9.8	9.5
6	5.63	5.6	5.6	5.53	5.75	5.75	5.9	5.8
7	0	0	0	0	6.375	6.175	6..1	6.18
8	5.72	5.62	5.54	5.68	0	0	0	0
9	6.75	6.6	6.75	6.425	6.367	6.333	6.367	6.6
10	5.625	5.85	5.725	5.925	5.73	5.73	5.73	5.73
11	4.93	4.9	4.93	4.967	4.67	4.77	4.73	4.77
12	8.1	8	8.3	8.4	0	0	0	0
13	6.05	6.2	6.15	6.05	5.85	5.95	5.85	5.8
14	6.025	6	5.975	5.95	0	0	0	0
15	5.7	5.7	5.65	5.7	5.4	5.8	5.7	5.7

APPENDIX I

The data in this table relates to the sensory component (S) and the affective component (A) of the McGill pain questionnaire scoring results for the control group from consultation one (S1, A1) through four (S4, A4). The numerator relates to the sensory or affective score and the denominator relates to the number of words chosen to obtain this score. Where there is no denominator, the number of words chosen is **one**.

PLACEBO McGILL PAIN QUESTIONNAIRE RESPONSES								
NO	S1	A1	S2	A2	S3	A3	S4	A4
1	6/3	2	3/2	0	1	0	2/2	0
2	3/2	4/2	8/3	2	5/3	2	7/3	8/3
3	3	5/2	1	1	2	0	1	0
4	4/3	0	5/3	0	5/3	0	6/3	0
5	13/6	2	3/2	1	4/3	0	2	0
6	5/3	0	2/2	0	2/2	0	2/2	0
7	5/3	1	3	1	4/2	0	4/2	0
8	8/4	2	8/4	3	6/4	2	8/4	0
9	26/9	8/3	19/7	9/3	14/7	2/2	30/10	12/4
10	4/2	0	4/3	0	5/3	0	5/3	0
11	5/2	0	7/4	2	6/4	1	6/3	0
12	13/5	3	12/4	5/2	12/5	3	11/5	5/2
13	9/6	0	8/4	1	6/3	0	6/2	0
14	6/4	1	6/3	1	6/3	1	5/4	1
15	14/5	0	11/5	0	10/4	0	9/5	0

APPENDIX J

The data in this table relates to the sensory component (S) and the affective component (A) of the McGill pain questionnaire scoring results for the treatment group from consultation one (S1, A1) through four (S4, A4). The numerator relates to the sensory or affective score and the denominator relates to the number of words chosen to obtain this score. Where there is no denominator, the number of words chosen is one.

TREATMENT McGILL PAIN QUESTIONNAIRE RESPONSES								
NO	S1	A1	S2	A2	S3	A3	S4	A4
1	2	1	1	1	5/2	3	3/2	1
2	10/6	5/2	13/6	2/2	12/5	2	6/4	4/2
3	10/6	1	7/4	2	6/4	1	5/5	1
4	6/3	1	1	0	4/2	1	3/2	0
5	5/2	1	0	0	2	0	1	0
6	4/3	1	O	O	O	O	O	O
7	7/4	0	4/3	0	10/4	0	2/2	1
8	6/3	2	6/3	0	3/2	0	11/5	0
9	9/4	0	6/4	2	11/5	4/2	7/4	0
10	11/6	0	4/3	0	4/3	0	3/3	0
11	4/2	0	2	0	5/4	0	6/3	0
12	8/4	4/2	9/4	1	6/3	3	13/6	0
13	2	1	2/2	1	3/2	0	3/2	1
14	6/2	0	2	0	3/2	0	7/3	0
15	7/4	1	11/4	3	1	0	4/3	0

APPENDIX K

The data in this table relates to the score recorded for the 101-point Numerical rating Scale for the placebo (P) and treatment (T) groups from consultation one (P1, T1) through four (P4, T4).

101-POINT NUMERICAL RATING SCALE SCORES								
NO	P1	P2	P3	P4	T1	T2	T3	T4
1	50	50	30	40	100	75	100	60
2	80	70	75	100	60	60	60	60
3	100	80	80	25	70	50	50	50
4	30	20	10	20	70	20	75	10
5	75	75	75	75	80	0	10	5
6	60	40	50	60	5	0	0	0
7	50	25	30	20	50	20	60	10
8	70	80	50	75	50	50	40	50
9	80	100	70	100	80	80	90	80
10	10	10	15	20	50	40	40	25
11	80	75	60	80	70	50	70	80
12	90	100	60	80	90	80	60	100
13	50	60	20	60	100	40	50	15
14	70	75	70	50	100	100	100	100
15	80	30	75	40	55	70	10	15

APPENDIX L

INFORMED CONSENT FORM

(To be completed in duplicate by patient/subject*) *delete non applicable.

Title of Research Project:

Name of Supervisor:

Name of Research Student:

PLEASE CIRCLE THE APPROPRIATE ANSWER

1. Have you read the research information sheet? yes/no

2. Have you 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 implication of your involvement? yes/no

8. Do you understand that you are free to withdraw from this study?
   a. at any time yes/no
   b. without having to give a reason for withdrawing yes/no
   c. without affecting your future health care yes/no

9. Do you agree to voluntarily participate in this study? yes/no

Patient/Subject* Name: _____

Signature: _____

Parent/Guardian* Name: _____

Signature: _____

Witness Name: _____

Signature: _____

Research Student Name: _____

Signature: _____

APPENDIX M

STANDARD DIAGNOSTIC CASE HISTORY

Date:

IDENTIFYING DATA

Name:

Date of birth and age:

Occupation:

MEDICAL HISTORY

Allergies:

Medication currently being taken including vitamins and supplements:

Travel within the last six months:

Vaccinations, childhood and within the last year:

Significant life events within the last three years e.g. bereavement, divorce:

Past surgical history:

Any operations or surgical procedures since birth:

Past medical history:

Major childhood illnesses:

Significant illnesses e.g. hepatitis, rheumatic fever or any other prolonged or severe illnesses:

Any illness or injury requiring hospitalisation:

Chronic or recurrent illnesses or complaints e.g. asthma, hypertension:

Family history:

Major illness of parents or siblings or deaths related to illness:

Family tendencies towards health problems e.g diabetes, hypertension, malignancies, arthritis, cardio-vascular disease:

MAIN COMPLAINT

Onset, duration, possible aetiology, location, radiation, character, related pain, previous treatment and investigations, modalities, concommitants, affect of illness.

Principal symptoms:

SYSTEMS REVIEW

General:

Weight change of more than 10 % within the last six months, malaise, fever, weakness.

Headaches:

Frequency, duration, location, modalities, concommitants, aetiology, pain description, radiation.

Eyes:

Glasses, pain, excessive tearing, redness, fatigue.

Ears:

Pain, hearing problems, tendency to infections, discharge, tinnitus, vertigo.

Nose and sinus:

Tendency to hay-fever or sinusitis, post nasal drip, irritating cough, nose bleeds, nasal discharge.

Mouth and throat:

Mouth ulcers, cracked lips, bleeding gums, frequency and nature of sore throats, swollen glands, dysphagia.

Respiratory system:

Tendency to infections, dyspnoea, wheezing, asthma history, cough, sputum, haemoptysis.

Cardiac system:

Any previous heart trouble or investigations, pain or discomfort, palpitations, murmurs, rheumatic fever, cardiac related dyspnoea or orthopnoea or paroxysmal nocturnal dyspnoea, oedema.

Diet:

Description of an average day's meals, cravings, aversions, salt intake, water consumption, thirst, fluid intake.

Gastrointestinal system:

Heartburn, anorexia, nausea, vomiting, regurgitation, haematemesis, constipation, diarrhoea, bloating or excessive passing of gas, food intolerance, previous liver or gallbladder illness.

Urinary system:

Nocturia, frequency, infections, incontinence, burning or pain on urination, haematuria.

Skin:

Rashes, warts, melanomas, eczema, psoriasis or other dermatological conditions.

Musculoskeletal:

Onset, location, description, timing and duration of stiffness, modalities, concommitants, pain description, radiation, possible aetiologies, previous injuries, swelling, previous investigations and treatment, affect on lifestyle, periods of exacerbation or remission, self help methods.

Peripheral vascular system:

Intermittent claudication, cramping, varicose veins, ulcers.

Genito-reproductive system:

Sexual activity, history of venereal disease, coital pain, discharges or masses.

Neurological system:

Syncope, blackouts, paralysis, peripheral neuropathies, tremors or other involuntary movements.

Haematological system:

History or tendency to anaemia, bleeding disorders or easy or prolonged bleeding, bruising.

Endocrine system:

Previous investigations or treatment for thyroid problems or diabetes or other endocrine related illnesses, heat or cold intolerance, weight changes, excessive sweating or thirst.

Psychiatric:

General information on interests, pleasures and pastimes, difficulties, worries, depression, crying, nervousness, medication or hospitalisation for psychiatric illness, memory loss, stress and tension, coping mechanisms. Sleeping patterns, dreams.

ON EXAMINATION

General observations:

Gait, posture, general state of health, body development, dress, grooming and personal hygiene, alertness, intelligence, reaction and response to questioning.

Vital signs:

Blood pressure

Pulse

Respiratory rate

Temperature

Weight and height

Chest:

Inspection of chest:

Signs of malformation, deviation. Skin rashes, chest wall movement. Auscultation of heart and lungs, palpation of cardiac borders, tactile fremitus, percussion.

Abdomen:

Inspection for signs of oedema, surgery, rashes, bloating. Light and deep palpation of the abdomen. Palpation for enlargement and or tenderness of liver, kidneys and spleen. Rebound tenderness, auscultation of abdominal sounds. Evidence of herniation.

Face:

Visual inspection. Ophthalmoscopic and otoscopic examination. Sinus and nasal illumination. Oral and throat illumination and inspection.

Lymphatic and endocrine:

Palpation of facial, occipital, neck, axillary and inguinal lymph nodes. Palpation and inspection of thyroid gland.

Musculoskeletal:

Neck stiffness. Signs of flaccid or spastic paralysis. Reflex testing of upper and lower limbs, dermatome and myotome testing of lower limbs.

Skin and general:

Warts, lesions, moles. Swelling and or oedema, skin colouring, ulceration, naevi. Halitosis. Mental faculties and awareness.

ADDITIONAL HOMOEOPATHIC QUESTIONS

Mind:

Tendencies to depression, crying. Better or worse for consolation. Stress and coping mechanisms. Obsessive or continual thoughts. Dream content. Fears and anxieties.

Modalities:

Best and worst time of day. Weather sensitivities and likes and dislikes. Better or worse for movement or rest. Place preferences i.e. inland or coast and affects there of. Thirst. Effect of meals or hunger on mood. Mood on waking and after catnaps.

DIFFERENTIAL DIAGNOSIS

APPENDIX N

Medication prescribed to treatment patients:

Patient number	Remedies
1	N.sulph.15, R.T.9, B.A.9
2	Lach.30, Sepia15, N.sulph15, B.A.9, Dulc.9
3	Aurum met.30, B.A.9, R.T.9
4	Lyc.30, B.A.9, Rad. brom.9, T.res9, Arn.9
5	Calc.phos.15, R.T.9, T.res9
6	Calc.F9, Lyc.15, Puls.9, B.A.9, R.T.9
7	Sil.15, R.T.9, T.res1000
8	Lach.30, B.A.9, R.T.9
9	N.sulph.15, B.A.9, R.T.9, Apis9, Kalmia9
10	K.carb15, B.A.9, R.T.9, Ruta grav.9
11	Theb.10M, N.sulph.15, B.A.9, Ruta9, Hyp.9
12	Ars.alb.30, B.A.9, Arn.9
13	Apis9, B.A.9, T.res.1000
14	Aurum.met.30, B.A.9, N.mur.9, T.res.1000
15	Sil.30, B.A.9, R.T.9, T.res1000

APPENDIX O

KEY FOR THE TABLE OF REMEDIES

Arn.	Arnica
Ars. alb.	Arsenicum album
Aurum met.	Aurum metallicum
B.A.	Bryonia alba
Calc.F.	Calcarea fluorica
Calc.phos.	Calcarea phosphorica
Dulc.	Dulcamara
Hyp.	Hypericum perfoliatum
Kali.carb.	Kalium carbonicum
Kalmia	Kalmia latifolia
Lach.	Lachesis mutus
Lyc.	Lycopodium clavatum
N.sulph.	Natrum sulphuricum
Puls.	Pulsatilla praetense
R.T.	Rhus toxicodendron
Rad.brom.	Radium bromatum
Ruta grav.	Ruta graveolens
Sepia	Sepia
Sil.	Silica
Theb	Thebiacum