KEY FACTORS FOR THE USE OF HOMOEOPATHIC REMEDIES AS AN ADJUNCT IN ASTHMA MANAGEMENT

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I, Eugene Lawrence Tak, do hereby declare
that this dissertation represents my own work
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Dedication

"This dissertation is dedicated to my wife and our children.
I wish to express my gratitude to Eleanor for being so
understanding and supportive of my studies.
To Jason, Xiang and Clinton, who have always brought us joy:
May you always surpass life's goals."

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Abstract

This study aimed to evaluate the use of homoeopathic remedies, as an adjunct to allopathic medicines, in the management of asthma. A double blind randomised placebo-controlled design was used in the trial. Thirty-two patients who were medically diagnosed as suffering from atopic asthma took part in the study. Certain limiting criteria such as age, smoking, pregnancy were used to focus the patients into a more homogenous group.

The patients selected for this trial were using only salbutamol, a bronchodilator, in a metered unit dose inhaler to treat their asthmatic symptoms. Limited use of additional medication was allowed, if asthmatic symptoms were exacerbated during the trial.

Both subjective and objective records were used to determine the efficacy of the homoeopathic medications used. The subjective data were collected using the Asthma Quality of Life Questionnaire (Marks, et al. 1992). Objective data were collected using daily Peak Expiratory Flow readings, salbutamol inhaler Pump Usage and Asthma Severity Scores (Woolcock and Jenkins, 1991).

A two-week "dry" run was initially performed allowing the patients to familiarise themselves with what was expected of them. This period also allowed the researcher to rectify any potential problems, before the actual study took place. During the study the treatment group was prescribed five *Poumon Histamine* 15CH pillules to be taken each morning on waking, five *House Dust* 30CH pillules to be taken at bedtime each night. Once a week, five pillules of a constitutional remedy in the 15CH potency, chosen out of a possible twelve, was prescribed.

A 5% level of significance was used in all cases of analysis. Statistical differences between the two groups became more significant as the study progressed. Notably, the mean asthma pump usage at the end of the study was significantly lower (P=0.016) for the treatment group (1,74 puffs/day) as compared to the placebo group (3,41 puffs/day).

Inter-group comparison of Asthma Severity score at the end of the study shows a significant difference in the scores between the placebo and the treatment group (P=0.019). The placebo group had a higher mean Asthma Severity score (9,8) compared to that of the treatment group

(7,14). The placebo group perceived that the severity of their asthma to be worse than that of the treatment group.

Intra-group comparison for asthma severity score showed that there was significant deterioration (P=0.01) in Asthma Severity scores in the placebo group. In the treatment group there was an improvement (P=0.100) in Asthma Severity score.

This study showed that there was significant improvement in asthma, in terms of asthma pump usage and asthma severity in the treatment group. The graphs showed a divergent trend with the placebo group deteriorating and the treatment group improving as the study progressed.

The results derived from this trial were encouraging. It was recommended that this study be used as the basis for further studies on the homoeopathic treatment of asthma. This study needs to be extended, in both the sample size and the length of the study, before recommendations for its definitive use as an adjunct in asthma management can be made.

Table of Contents

List of Tables

List of Graphs

Chapter 4:Results

Definitions

Allergodes

Allergodes are defined as isopathic remedies used to treat allergies (Kayne, 1997: 101).

Constitutional Type

"Classification according to which a particular medicine suits a specific kind of person" (Gaier, 1991:103).

Homoeopathy

"A self-contained scientific system of medicinal therapy, based on the observed biological fact that a diseased deviation from an organism's bioenergetic mean, within reversible limits, can predictably be restored to normal by specially prepared medicinal stimuli, that need only be administered in small doses, or more often in sub-physiological deconcentrations, owing to an altered receptivity of tissue to such stimuli in disease, provided always (a) that in healthy organisms the medicinal agents chosen would produce symptoms and clinical features like those of the

disease, and (b) that obstacles to cure have been removed" (Gaier, 1991:272).

Isopathy

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

Isotherapy

"Therapeutic method based on administrating infinitesimal potentizations of substances taken from the patient or from his or her environment and having a direct connection with the morbid manifestations" (Demarque and Joly, 1986: 202).

Potentization

"This is a physical process through which latent curative powers of medicines are aroused into activity, though these may have been inevident in their crude states" (Gaier, 1991: 444).

Placebo

In homoeopathic practice, it refers to a non-medicated substance, which is relatively pharmacodynamically inert (Gaier, 1991: 426).

Polychrest

These are remedies whose drug picture exhibits a wide spectrum of activity and therefore have a broad range of applications (Kayne, 1997: 99).

Proving

"Term used in Homoeopathy to designate all of the symptoms produced by experimental administration of a given drug to a healthy individual who is sensitive to the substance being studied" (Demarque and Joly, 1986: 204).

Repertorization

A process used to find the homoeopathic remedy which best parallels the majority of symptoms exhibited by the patient (Gaier 1991: 493-494).

Therapeutic index

This is the dose ratio between toxic and therapeutic effects. In animals, it may be expressed as the ratio LD50/ED50, where LD50 is the dose lethal to 50% of a population and the ED50 is the dose therapeutically effective in 50% of a comparable population. (Berkow, 1982: 2284.)

Chapter 1: Introduction

From the beginning of time, *breath* has been fundamentally important to all living things. According to the *Holy Bible* (Genesis 2: 7), "And the Lord God formed man *of* the dust of the ground, and breathed into his nostrils the breath of life; and man became a living soul."

The word asthma is derived from the Greek language, and means "to pant". This describes the shortness of breath associated with this condition. Aretaeus in the second century, already described the rapid noisy breathing of the asthmatic, and also the anxiety and fear which it induced. (Lane and Storr, 1981: 18-19.)

Jeena, et al. [s.a.] concede that asthma is one of the most common respiratory complaints. It affects one in ten children and one in twenty adults. Further more, they say that asthma cannot be cured as yet, but may be controlled. This is the case in spite of the fact that asthma is the commonest chronic disease affecting both adults and children in the developed world (Murcheson, 1995). "Asthma affects over 100 million people world-wide and creates a burden in health care costs and lost productivity" (Vine, 1998: 107). Gleick (1997) illustrates that the

indirect costs of asthma treatment may almost be as high as the direct medical costs. In the case of the United Kingdom, they show that the indirect costs, which relate to loss due to illness, including absence from work, may be more than the direct medical costs. In 1988 the direct medical costs in the United Kingdom was estimated to be US$722.5 million, whilst the indirect costs were estimated to be US$1.07 billion.

Drugs may be used to control the symptoms of asthma, but it seems that the cheaper the drug, the more prevalent the side-effects are. Theophylline has been used as a bronchodilator for 45 years and is probably the most commonly prescribed drug for asthma. Theophylline, however, has a low therapeutic index. (Edinburg, 1998.)

Summers (1992) says that long term use of β_2-agonists are no longer favoured in some circles, because of increased morbidity and mortality. This may be a consequence of the fact that regular use of β_2-agonists may result in increased airway inflammation, and the formation of hyper-responsive scar tissue. An acute condition may then become chronic and irreversible. Edinburg (1998) even goes as far as to say that repeated, excessive use of β_2-agonists may result in paradoxical bronchospasm.

According to Edinburg (1998) corticosteroids are used to prevent asthma attacks. She lists the Cushingoid appearance, growth suppression, cataracts and muscle weakness as some of the side-effects associated with corticosteroid use. She adds that the toxicity of corticosteroids depends more on the duration of use, than on the dose. Gleick (1997) maintains that bronchodilators and corticosteroids have been available for the control of asthma for about 20 years. She also observes that there are limitations: these medications only suppress the condition, they do not cure it.

Van der Kooy (1999) says medical costs are rising faster than inflation by a factor of about 16% per year. However, according to Halberstadt (1999): ".... of concern are not those who have medical aid cover, but those who cannot afford the most basic of asthma medication".

According to Wallace (1986), there are no known acute reactions to the administration of homoeopathically prepared allergens recorded. This is further supported by Ernst (1995: 193) who says, "Homoeopathy is a low-cost, non-toxic system of medicine". He does, however qualify his statement, by saying that adverse drug reactions to homoeopathic medicine is rare, but we must weigh the benefits against the risk when prescribing any form of treatment.

medicine is rare, but we must weigh the benefits against the risk when prescribing any form of treatment.

Kayne (1997: 117) maintains that there is no evidence that homoeopathic remedies interfere with allopathic medicines. Hence, homeopathic and allopathic medicines may be complementary.

A meta-analysis on 107 controlled trials in humans was conducted by Kleijnen, et al. (1991). The aim of the study was to evaluate the methodological quality of these trials. Five of the 107 assessed trials involved allergic reactions. All five of these trials on allergy had positive outcomes.

Positive results for homoeopathy were also reported for studies on allergic conditions by Reilly, et al. (1986), Poolman (1994), Beattie (1996), and Opperman (1997). A retrospective evaluation of the homoeopathic treatment of 62 randomly selected asthma patients was done by Eizayaga, et al. (1996). They reported that homoeopathic medicines were effective in the treatment of asthma.

Although a number of studies have been done on atopic diseases, very few have been done specifically on asthma. Homoeopathic studies on

asthma often take the form of descriptions of successful case histories (Gnaiger, 1990). Gnaiger (1990: 135) even goes as far as to say, "Successful treatment with a homoeopathic drug may be considered scientific proof (of its effectiveness)." Often studies take the form of retrospective evaluations of the efficacy of homoeopathic medicines, because they need relatively fewer resources (Castellsagu, 1992).

It can be seen that available medical drugs are effective in asthma management. Their side-effects and high cost are, unfortunately their largest disadvantages. The above evidence shows that homoeopathic medicines may hold the answer to a safe and cost effective way of treating asthma. This is especially important in countries where the population cannot afford the more expensive and sophisticated drugs.

With the above in mind, this double blind clinical trial aims to determine the efficacy of homoeopathic medicines in the treatment of asthma, in terms of its clinical manifestations and patient perceptions. These remedies are homoeopathically prepared *lung histamine* and *house dust*, and a constitutional remedy. This allowed us to determine how key factors are influenced when homoeopathic remedies are used as adjuncts in asthma management.

Chapter 2:

Review of the related literature

2.1 Introduction

Kayne (1997: 10) observed that there was an increased demand for homoeopathy. He noted that in the United Kingdom the demand has increased by 50% between 1991 and 1994. He suggests that this increased demand was due to a number of factors. Amongst these factors was the fact that complementary medicine was perceived to have a more acceptable risk:benefit ratio. Further more, homoeopathy also appealed to patients, because they felt that more attention was taken of other aspects of themselves, and not only of their disease. The presenting symptoms were not the only aspects taken into consideration. Some patients were dissatisfied by the low efficacy and side effects of allopathic medicines. The media also seemed to encourage patients to seek alternative treatments. Complementary medicine is seen to be 'natural', and hence appeals to the 'green' lobby.

The cost of medication also plays an important role in the increased demand for homoeopathic medicines. The net ingredient cost is substantially less than the cost of the newer orthodox medicines. (Kayne, 1997: 11.)

2.2 Relevant pathophysiology

There is no precise definition of asthma, but in older children and adults, it is considered to be a chronic inflammation of the airways (Paton, 1998).

Newman, et al. (1995: 710) define asthma as "narrowing of the airways that is reversible over a short period of time, either spontaneously or as a result of treatment." This definition emphasises the reversibility of the airway narrowing in asthma, as opposed to the less reversible narrowing of other respiratory conditions. Edwards and Boucher (1991: 376) describe bronchial asthma as paroxysms of breathlessness, chest tightness and wheezing, resulting from narrowing of airways. This, according to them, is as a result of muscle spasm, mucosal swelling and viscid bronchial secretions.

Kumar, et al. (1997: 395-397) say asthma is a heterogeneous disease, which has a multitude of triggers. It can however be divided into two main categories depending on whether there is an underlying immune disorder or not: namely, extrinsic and intrinsic asthma.

A. Extrinsic asthma

Exposure to an extrinsic antigen initiates a *type-1* hypersensitivity reaction. This results in the production of Immunoglobulin E (IgE). Atopic asthma is the most common type of asthma and is associated with other allergic manifestations.

B. Intrinsic asthma

Here the triggering mechanism is not immunologically based. Triggers of intrinsic asthma may also trigger an asthma attack in a patient suffering from extrinsic asthma. So the border between intrinsic and extrinsic asthma is not distinct.

The common factor in all forms of asthma is the increased airway reactivity. This can be demonstrated by the increase sensitivity of

asthmatics to bronchoconstrictors like histamine and cholinergic agonists.

Atopic asthma like all *type-1* hypersensitivity reactions, is driven by sensitisation of CD4+ cells of the class II helper T-cells (T_H2) type. The T_H2 cells release cytokines like Interleukin-4 (IL-4) and Interleukin-5 (IL-5). This favours the synthesis of IgE. Interleukin-4 stimulates the growth of mast cells, while IL-5 causes growth and activation of eosinophils. Direct sub-epithelial vagal stimulation provokes reflex bronchoconstriction. Mast cell activation leads to the release of a number of mediators. The most important being leucotrienes, prostaglandins, eosinophils and platelet activating factor. Platelet activating factor causes platelet aggregation and the release of mediators from their granules. These mediators induce broncho-constriction, oedema and mucus secretion. There is also evidence of bronchial basement membrane thickening. Hypertrophy and hyperplasia of the smooth muscle cells are also involved. (Kumar, et al. 1997: 395-397.)

It has recently been found that inhaled leucotrienes cause the classical pathophysiology in atopic asthmatics. That is, bronchoconstriction and

an increased sensitivity to histamine. They also cause increase in airway micro-vascular permeability. This leads to oedema, mucosal thickening and mucus secretion. (Van Schoor, 1999c.)

Atopic asthma generally effects individuals who readily form IgE antibodies to commonly encountered allergens. These allergens are usually organic in origin and include pollen, house dust mites, feathers, danders and fungal spores. (Edwards and Boucher, 1991:376.) Rusznak (1999) says allergen avoidance is the basis for the management of all allergic diseases. Exposure of infants to more than 10mcg of Der p1 (a major mite allergen) per gram of household dust, during infancy is associated with almost a five-fold risk of developing asthma by the age of eleven.

Evidence indicates that there may be a genetic basis for atopic asthma. It is widely accepted that asthma is an inheritable disease. There is an increased prevalence of asthma amongst relatives of asthmatics as compared to non-asthmatic subjects. Both genetic and environmental factors play a role in the pathogenesis and development of the disease. It is hypothesised that a defective β_2-adrenergic receptor may be responsible for asthmatic symptoms. In 1989 the first evidence of a

relationship between atopy and a specific chromosomal region was found. (Holloway, et al. 1999.)

2.3 Incidence and prevalence.

The prevalence of asthma has risen over the past few decades and is estimated to affect 1.5million children in the UK (Paton, 1998: 34). Prevalence of asthma may be as high as 11% in some countries. These high rates make asthma one of the commonest adult diseases and the most chronic disease in children. (Ehrich, 1998: 4.)

Air pollution is a contributing cause of asthma. In fact, the morbidity of asthma increases in tandem with increasing air pollution. It has been shown that in southern California, up to 17% of school going children suffer from asthma. It is also evident that air pollution inside homes contributed to breathing problems. On this basis it has been recommended that air borne hazards within the home be reduced. These include tobacco smoke, animal derived allergens, and mould. Pollution in the industrial areas south of Durban has been found to be four times higher than the World Health Organisation's limits. (Reuters, 1999: 12.)

2.4 Clinical considerations and differential diagnosis

Asthma and chronic obstructive pulmonary disease (COPD) have similar symptoms and the two conditions can be difficult to differentiate. Asthma patients often report attacks of breathlessness at rest, whilst COPD sufferers only experience breathlessness after exertion. Asthma is typically variable and episodic, whilst COPD is slow and progressive. Chronic bronchitis and emphysema may also mimic asthma. (Smith: 1998.)

2.5 Comparison of treatments

2.5.1 Allopathic Treatment

Inhaled corticosteroids are the cornerstone of asthma management. The inhaled dose may vary by a factor of four, depending on technique and devices used. There are also concerns about the side effects of the newer high dose corticosteroids. Side effects include adrenal suppression, osteoporosis, cataracts, glaucoma and growth retardation in children. (Van Schoor, 1999b.) Halsey (1999) states that osteoporosis is a major complication of corticosteroid therapy and an important cause of morbidity. Further, the precise mechanism by which corticosteroids causes osteoporosis is not known. According to him, there is some

evidence that there is a decrease in osteoblastic bone formation and an increase in osteoclastic bone resorption. According to Woolcock and Jenkins (1991) the above effects are less pronounced with inhaled corticosteroids as opposed to orally administered steroids. Inhaled steroids are also shown to cause dysphonia in 15% of patients, which may be due to local steroid induced myopathy. Some patients may develop oral thrush from inhaled corticosteroids, because of immune suppression.

β_2-agonists act on bronchial smooth muscle, causing relaxation and dilation of narrowed airways. There may also be some stabilization of mast cells; retarding mediator release. There is some concern with the long-term use of β_2-agonists. They are shown to be associated with worsening asthma when used regularly. It was reported from New Zealand that there have been a number of deaths in young asthmatics due to fenoterol use. (Woolcock and Jenkins, 1991.)

It is thought that the long-term use of β_2-agonist may be harmful to asthma patients. Bronchial hyper-responsiveness increases, when β_2-agonist are used as the sole means of asthma management. It is possible that the use of higher potency bronchodilators may mask worsening

asthma symptoms. Bronchodilators may result in a delay in recognising the severity of the attack and in seeking medical help. (Bartlett, 1991.)

For over 50 years theophylline has been used in the management of chronic asthma (Theophylline revisited: 1997). Theophylline is considered a weak bronchodilator and has a narrow therapeutic window. This narrow range between the therapeutic and toxic dose has led to the diminished use of theophylline. At plasma levels, considered to be below the therapeutic range, theophylline was shown to have anti-inflammatory and immuno-modulating properties. The side effects of theophylline include anorexia, nausea, headache and palpitation. In children, hyperactivity, poor attention span and insomnia may be evident. The concurrent use of many drugs decrease the elimination of theophylline, leading to an increase in side-effects and toxicity. (Woolcock and Jenkins, 1991.)

Antileukotrienes are the first new class of drugs in 25 years for the asthma management. They include leucotriene antagonists and 5-lipoxygenase inhibitors. 5-Lipoxygenase inhibitors inhibit enzymes necessary for the conversion of arachidonic acid into leucotrienes. Cysteinyl-leukotrienes (cys-LTs) are said to be a thousand times more potent as a bronchoconstrictor compared to histamine. Leucotriene

antagonists are a recent addition in the fight against asthma in patients over 12 years of age. When leukotrienes are inhaled by asthmatics, the classic pathogenesis of asthma is induced. Zafilukast®, is a new orally active leukotriene receptor antagonist. It inhibits bronchoconstriction induced by an allergen challenge, cold air and exercise. Leucotriene antagonists improve asthma control, in cases which are poorly controlled by high doses of cortisones. Leucotriene antagonists are generally well tolerated, but side-effects like headaches, nausea and diarrhoea are evident. They are not suitable for use during breast-feeding or pregnancy. (Barnes, 1997.)

Barnes (1997) further says that asthma is a highly complex inflammatory disease process involving many inflammatory cells, mediators and inflammatory effects. He further observes that drugs that target only one aspect of this disease are unlikely to be highly effective.

Seretide® is a novel combination of salmeterol and fluticasone propionate for the treatment of asthma. The combination of a long acting β_2-agonist and a corticosteroid in one inhaler allows the patient to control the symptoms of asthma for up to 12 hours. This allows for better patient compliance. (Ehrich, 1998: 4.)

Immunotherapy, intravenous theophylline, sedatives, tranquillisers and chest physiotherapy are labelled as hazardous or ineffective therapy by Woolcock and Jenkins (1991). This is especially true for acute asthma attacks. Mucolytics and ionisers are ineffectual in the treatment of childhood asthma. The efficacy of antibiotics is also questioned, since acute attacks of asthma are often precipitated by viruses. Antibiotics should only be prescribed in the uncommon situation where a bacterial super-infection is evident. (Woolcock & Jenkins, 1991.)

2.5.2 House dust mite reduction

House dust mites, and especially their excrement, are a contributing factor in allergic asthma. Tests based on the gaunine content of house dust mite excrement have been developed. If house dust mites are found to be a problem, they may be removed using benzlbenzoate based solutions, powder, foam or sprays (Allergopharma, [s.a.]).

Allergen avoidance is a cost-effective way to control atopic asthma, however this may disrupt a patient's life style. For example, the patient may have to get rid of the family pet. (Morice, 1998.)

2.5.3 Medicinal Plants

The leaves of both *Leonotis leonurus* (Wild dagga) and *Datura stramonium* (Thorn apple) have been used to treat asthma. These medicines do also have side effects. The leaves of *Leonotis Leonurus* are mildly narcotic. *Datura stramonium*, especially the seeds, is highly hallucinogenic. The *Datura stramonium* leaves may be rolled and smoked to relieve asthma. These plants are either harvested in the wild or cultivated. (Yeld, 1999.) According to Roberts (1990: 223), *Leonotis leonurus* flowers are used as a tea to treat respiratory complaints, including asthma.

2.5.4 Food and dietary supplementation

Werbach (1992a) maintains that food sensitivities are a common cause of asthmatic symptoms in people suffering from perennial asthma. He suggests that patients with perennial asthma be put onto an antigen-free diet for two to three weeks. If the patient responds to this diet, he suggests that they be given betaine hydrochloride or glutamic hydrochloride to increase gastric hydrochloride content. He bases his recommendation on the fact that asthmatic patients are more inclined to hypochlorhydria compared to non-asthmatics.

Werbach (1992b) further suggests that in an emergency, where professional help is not available, the patient should drink a few cups of coffee. Rall (1980: 592-593) says that theophylline, caffeine and theobromine are closely related alkaloids known as xanthines. According to him, they share common pharmacological actions including: diuresis, central nervous system stimulation, cardiac stimulation, and smooth muscle relaxation; notably bronchial smooth muscle.

It has been shown that a diet rich in oily fish, reduces the risk of developing asthma in children. The mechanism is thought to be due to a higher ratio of omega-3 (eicosapentaenoic acid), as opposed to omega-6 (arachadonic acid) fatty acids being deposited into the phospholipids of the cell membranes. Eicosapentaenoic Acid (EPA) also competes with arachadonic acid as a substrate in the manufacture of mediators such as leukotrienes, thromboxane and prostaglandins. This results in a decreased activation of inflammatory cells, decreased broncho-constriction and decreased mucus secretion. (Van Schoor, 1998.)

Werbach (1992c) found that magnesium is able to relax muscle, even smooth muscle. He says that injected magnesium may abort acute

asthmatic attacks. Further, inhaled magnesium is found to reduce the ability of both histamine and metacholine to produce bronchospasm in asthmatics.

Hart (1993) writes that 43% of asthmatic children at the Red Cross Children's Hospital developed a tight chest due to a common food preservative, sulphur dioxide. Sulphur dioxide and other sulphites are also used to spray fresh produce in supermarkets and to condition dough in bakeries. It is also used as an anti-microbial agent in soft drinks, beer and wine. He further observes that the severity of the tight chest was proportional to the amount of preservative ingested.

From the above it can be seen that food, food supplements and food additives do play a role in amelioration and exacerbation of asthma symptoms.

2.5.5 Acupuncture Treatment of Asthma

Acupuncture has been used for over 5000 years (Chang 1976: xvi). Xinnong (1987:385-387) explains the different causes of asthma and their treatments according to traditional Chinese diagnosis. According to him asthma is of two types. The excess type is due to exogenous

pathogenic factors, whilst the deficiency type is due to a patient's weakened resistance.

Manning and Vanrenen (1988: 4-9) say that Chinese medicine and homoeopathy share theoretical and practical links. Both these philosophies of medicine depend on the healing power inherent in the body. This inherent power of self-healing depends on an energy which regulates and vivifies life. Chinese call this energy *Chi*, in homoeopathy it is called the *Vital Force.* Manning and Vanrenen (1988: 9) referred to this energy as *Bioenergy*. According to them this energy may be manipulated using acupuncture or homoeopathy to restore the body to health.

2.5.6 Homoeopathic Treatment of Asthma

Kleijen et al. (1991) meta-analysed 107 controlled homoeopathic trials to assess their methodological quality. One hundred and five of the original 107 trials had interpretable results. Eighty-one of these 105 trials reported positive results for homoeopathy, as opposed to the 24 trials where no positive effects were found. There were a large number of positive results, even in trials which received high quality ratings for randomisation, blinding, sample size, and other methodological criteria.

Five of the 105 assessed trials were studies on allergic reactions. All five of these studies had positive outcomes.

A subsequent meta-analysis was done by Linde et al. (1997) to determine whether the clinical effect reported in randomised controlled trials of homoeopathic remedies is equivalent to that reported for placebo. One hundred and eighty six homoeopathic trials were reviewed. Of these 89 were found to have adequate data for meta-analysis. They concluded that the results of their meta-analysis are not compatible with the hypothesis that the clinical effects of homoeopathy are completely due to placebo. They suggest that the evidence in their analysis would be more compelling, if there were independently replicated, large-scale rigorous trials of defined homoeopathic approaches in at least a few specific disorders.

Of further interest in the trial by Linde et al. (1997), was that the pooled odds ratio (95% CI) was 5.04 (2.24,11.32) for isopathy. When compared with classical homoeopathy, clinical homoeopathy and complex homoeopathy, isopathy had the highest odds ratio. This indicates that isopathy was favoured highest over placebo, when compared to the other sub-groups of homoeopathy.

According to Weinberg (1995) allergic reactions may, depending on the organs targeted, cause asthma, allergic rhinitis, atopic eczema, urticaria, angioedema or food allergies. Poolman (1994) found that homoeopathic medicines were effective in the treatment of allergic rhinitis. A study by Opperman (1997) showed that homoeopathic medicines were effective in the treatment of atopic eczema.

Pulmo is a homoeopathic sarcode, which is derived from the lungs of healthy animals. It is recommended for the treatment of pulmonary problems such as asthma, bronchitis and emphysema. (Reckeweg, 1983: 352-353.) In this study a homoeopathically potentised *lung histamine* was used as a homoeopathic antihistamine. In this context, *lung histamine* was used as an isopathic remedy (Gaier, 1991: 290). According to Gaier (1991: 290) isopathic remedies are made from the exact product which shows a causal relationship with the disease. Histamine is one of the products of mast cell degeneration due to an antigen-IgE reaction (Murcheson, 1995). According to Edwards and Boucher (1991: 37), histamine causes vasodilation, increased capillary permeability, chemokinesis and bronchoconstriction. Further, these effects of histamine are responsible for much of the pathophysiology of atopic asthma.

In a small pilot study, subcutaneously injected potentized *histamine* was found to increase serum cortisol levels of patients. The cortisol levels in one of the patients remained abnormally high for several months (Ward, 1995).

Krishnamurty (1984) says that asthma is an acute exacerbation of a chronic disease. According to Dutta (1984), all chronic diseases have their origins in the chronic miasms viz., psora, sycosis and syphylis. Krishnamurty (1984) goes on to say that there are successful homoeopathic practitioners who treat asthma using keynote prescriptions of anti-sycotic remedies. He further says that, unless the prescription is based on the totality of symptoms, the disease cannot be cured according to the homoeopathic definition of the word.

Wallace (1986) used anti-psoric remedies, constitutional remedies and desensitization remedies to treat the triad of asthma, eczema and hay fever. Skin tests were used to determine the desensitising remedy. He also says that the above triad of conditions have a very strong inherited tendency, indicating the psoric miasm.

According to Gaier (1991:103) constitutional prescribing was used to simplify homoeopathic diagnostics. It was used to classify patients

according to their temperaments, appearance, characteristics and their variance from normal. These patients seem to respond to a corresponding polychrest.

Some homoeopaths condemn the practice of prescribing constitutionally (Gaier 1991: 105). Hahnemann, himself, emphasises that the totality of the patient's symptoms must be the physician's principle concern (Kunzli et al. 1983). However, according to Gaier (1991:104) constitutional remedies can increase a patient's *vital energy*; thus increasing resistance, improving well-being, prevents relapses and facilitates deteriorated physiological and biological functions.

According to Casserley (1996) the homoeopathic responses should be, in order of importance: constitutional responses, hereditary predisposition, environmental factors, infective factors and triggering factors. Treatment of asthma by means of allopathic medication results in a *complex disease*. This complex disease arises, according to Hahnneman, from the addition of an iatrogenic disease to the original cause of the asthma (Kunzli et al. 1983: 40). Casserley (1996) states that the most common constitutional remedies for the treatments of asthma are: *Arsenicum album, Sulphur, Phosphorus, Natrum sulphuricum, Hepar sulphuris calcareum, Kali carbonicum and Bryonia alba.*

Although Hahnemann forbade the use of more than one remedy at once, he saw a place for using more than one remedy as part of a total prescription. This was especially true in his latter years in Paris. (Kayne, 1997: 112.)

Eizayaga, et al. (1996), did a retrospective evaluation of the homoeopathic treatment of 62 randomly selected asthma patients. They found that there was a statistically significant improvement in their patients. Their findings confirm the satisfactory, if not surprisingly good results obtained by homoeopathic physicians. They divided the patient's symptoms and characteristics into three groups: symptoms and characteristics of the attack, fundamental symptoms and constitutional features. The ideal remedy would be that which covered all three groups of symptoms. If this was not possible, an initial remedy that suited the characteristic symptoms of the asthmatic attack was chosen. To complete the treatment, a remedy covering the second, and later the third symptom picture was prescribed. Only one remedy was given at a time. Nosodes were however, sometimes prescribed in addition to a constitutional remedy. The remedies were frequently changed as the symptom picture changed.

Eizayaga, et al. (1996), say that there does not appear to be any adverse effects with the concurrent use of homoeopathic and allopathic drugs. They suggest that this concurrent use seems to be synergistic, and that allopathic and homoeopathic medicines be used concurrently in the case of serious attacks, or if improvement is not rapid. They do intimate, however, that the use of cortisone should be avoided if possible.

Prolonged tissue inflammation occurs during the late phase allergic reactions, resulting in the characteristic pathological changes associated with common allergic disorders. Depending on the tissues involved, these include asthma, allergic rhinitis, atopic eczema, urticaria, angioedema and food allergies. (Weinberg 1995.) Mead (1999) states that most people with asthma also have allergic rhinitis. The latter usually precedes the former and, like in the case of asthma, one of the commonest triggering factors is the house dust mite.

A number of studies have shown that homoeopathy is effective in treating allergic conditions. Beattie (1996) used homoeopathically prepared *house dust* and *house dust mite* to treat allergies at the Glasgow Homoeopathic Hospital. The experience gained from this was extrapolated to a study, which compared the effects of three different regimens of isopathic preparations used to treat allergies. The isopathic

remedies used for treating each patient were chosen according to the results obtained from a skin test (Standard Bencard Skin Test). All patients were tested for house dust, house dust mite, grass pollens, tree pollens, weeds, cat and dog dander, feathers, *Alternaria* and *Cladosporium*. Other potential allergens indicated by the patient history were also tested. It was found that isopathic remedies prescribed for allergic reactions had an objective, beneficial effect. Kayne (1999), a co-researcher in this study, said that the results obtained from this method of treating allergies were very good. According to Kayne, further work is being done on this study, at the Glasgow Homoeopathic Hospital, by Beattie and himself.

Reilly, et al. (1993) used homoeopathic allergen in the 30C dilution. Based on the Homoeopathic Immunotherapy (HIT) model they demonstrated that homoeopathic preparations show a clinical effect over and above their placebo action. They concluded that there was potential for using HIT as a substitute of conventional desensitisation.

In another study, Reilly, et al. (1986) showed that a 30CH potency of homoeopathically prepared mixed grass pollens was effective in treating patients with active hayfever. Poolman (1994) found that homoeopathically prepared mixed grass pollens, and especially in

combination with the homoeopathic *similimum*, were effective in the treatment of seasonal allergic rhinitis.

2.6 Cost implications of asthma management

Medical funds are concerned that the cost of health care is sixteen percent higher than for the previous year. The rise in the medical component of the consumer price index (CPI) is higher than that of the general index. This trend is likely to increase in the next few years. It is predicted that an employee's healthcare expenditure could account for 35% of their gross income in the next five or six years. (Van Zyl, 1999.)

According to Halberstadt (1999), the poorer sectors of our community are of more concern. At present they cannot afford the more expensive asthma medications. This is especially true of the inhaled bronchodilators and corticosteroids. They can only afford cheaper oral bronchodilators, which do not address the inflammation associated with asthma. Oral corticosteroids are relatively inexpensive, but a prescription is required. Their side effects are more pronounced than the inhaled corticosteroids, which have a more localised effect. Halberstadt(1999) further maintains that this inadequacy in asthma management, leads to decreased productivity and quality of life. Of

greater concern to him, is the increase in morbidity and mortality of these patients.

2.7 Measuring instruments

2.7.1 Objective Data

2.7.1.1 Peak Expiratory Flow (PEF) Readings.

It is recommended that patients actively manage their asthma by regularly monitoring their lung function using peak expiratory flow meters. PEF meters are relatively inexpensive, fast, portable and patients can monitor their own lung function on a regular basis. Peak flow rates vary between individuals. This variation is dependent on age, height and gender. PEFR tend to exhibit diurnal variations: being lower in the early morning and higher in the early evening. (Van Schoor, 1994.)

2.7.1.2 Asthma Severity Score

The Asthma Severity Score was designed by Woolcock and Jenkins (1991) to assist asthmatics to manage their asthma more effectively.

Patients were advised to use a stepwise regimen for the medical treatment of their condition:

- A score of 5 or less is said to be "mild", and may be treated with an inhaled bronchodilator on a "when necessary" basis.
- Patients scoring between 5 and 8 are considered to be "moderate" asthmatics. It is recommended that these patients should use *sodium cromoglycate* prophylactically, and if required, their bronchodilator pump.
- Those scoring above 8 are said to be "severe" asthmatics. It is recommended that these patients use a corticosteroid inhaler in addition to their bronchodilator pump.

The Asthma Severity Score is determined by the sum of:

- The Symptom Score.

  This is scored out of a possible 4. It depends on the frequency of attacks and also whether the patient experiences attacks at night.

- Bronchodilator Usage Score.

This is scored out of a possible 4. It is determined by how often a bronchodilator is used.

- The PEF variability.

  This is scored out of a possible 4. It is determine by the best and worse PEF readings of the day.

This yields a score out of 12. The higher the value, the more severe the asthma.

2.7.2 **Subjective data**

2.7.2.1 Asthma Quality of Life Questionnaire (Appendix D)

Several asthma questionnaires have been developed with special reference to asthma. The St. George's Respiratory Questionnaire (SGRQ) and the Asthma Bother Profile (ABP). The ABP covers the patient's worries and anxieties, whilst the SGRQ emphasises the asthma symptoms. Both these questionnaires are used as pre-interview questionnaires. They are used to facilitate and formulate questions during asthma interviews. (Barnes and Jacobs, 1995.)

The Asthma Quality of Life Questionnaire (Marks et al., 1992) was the preferred questionnaire to record subjective data. The measurement of

quality of life in relationship to asthma, covers aspects of the disease which pathophysiological and clinical markers do not adequately cover. This is a self-administered questionnaire used before and after intervention. It is suitable for patients who are 15 years old or older. Each response is scored from 0 (not at all) to 4(very severely) on a 5 point Likert scale. The values are not weighted. The twenty individual item scores are added to yield a score out of 80.

Four sub-scale scores may be determined:

BREATHLESSNESS	ITEMS 1 TO 5
MOOD DISTURBANCE	ITEMS 6 TO 10
SOCIAL DISRUPTION	ITEMS 11 TO 17
CONCERNS FOR HEALTH	ITEMS 9,11,14 AND 17 TO 20.

2.8 Summary

Modern drugs are powerful chemicals, which control specific molecular functions: this is where their strength and weakness lay. Their strength is in emergency medicine, surgery and infectious disease. Modern medicine has advanced little in the treatment of chronic diseases. Chronic diseases may be controlled to some extent by modern drugs, but not cured. (Manning and Vanrenen, 1988: 21-22.)

Asthma is a highly heterogeneous disease. The aetiology and triggers are numerous. There are a wide variety of the mediators precipitating the asthmatic pathophysiology. Each discipline of healing claims to be able to treat asthma. Even within each discipline there are different modalities and regimens for the treatment of asthma. The homoeopathic treatment of asthma seems the most varied and each practitioner seems to favour his own regimen. Yet, many practitioners and studies claim to be successful in the management of asthma using homoeopathic medicines.

It was with the above in mind that a safe and cost effective regimen for asthma management had to be found. This study aimed to evaluate the use of homoeopathic remedies, as an adjunct to allopathic medicines, in asthma management. It was envisaged that this would facilitate the design of a treatment for asthma, which is more economical, easy to administer and freely available.

Chapter 3: Materials and Methods

3.1 Study design

Thirty-two patients with clinically diagnosed atopic asthma were recruited from the Durban area and surroundings. Advertising posters (Appendix A) were placed in pharmacies, health shops, at the University of Durban-Westville, Natal University and Technikon Natal.

3.2 Location of data

The objective and subjective data were obtained from the patients taking part in the study:

3.2.1 Peak Expiratory Flow Readings

Patients were required to note the best of three peak expiratory flow meter readings and mark the highest reading on the scale provided. These readings were taken each morning on waking, before any inhaled salbutamol was used.

3.2.2 Pump Usage Score

The number of puffs of salbutamol inhalant used in the previous 24 hours was recorded on the provided record sheet (Appendix C).

3.2.3 Asthma Quality of Life Score

After the "dry" run the patients were required to fill in a "Asthma Quality of Life" questionnaire (Appendix D). The questionnaire was again completed at the end of the study.

3.2.4 Asthma Severity Score

The "Asthma Severity Score" must be determined by the patient and noted on the record sheet (Appendix C) on four designated Sundays.

3.3 Study design and protocol

This was a double blind clinical trial in which the control group received inert lactose pillules throughout the study. The treatment

group received placebo pillules for the first two weeks to obtain a base line. For the next 8 weeks the treatment group received:

Poumon Histamine 15CH - 5 pillules each morning.

House Dust Allergen 30CH - 5 pillules at bedtime.

Constitutional Remedy 15CH – 5 pills weekly on Sunday Morning.

A new batch of either, the placebo pillules or medicated pillules, were issued to the patients when they received each record sheet. The placebo group received unmedicated pillules according to the same regimen as for the treatment group.

For ease of dispensing the following 12 polychrests were used:

Argentum nitricum 15CH

Arsenicum album 15CH

Calcarea carbonica 15CH

Lycopodium clavatum 15CH

Natrum muriaticum 15CH

Natrum sulphuricum 15CH

Nux vomica 15CH

Phosphorus 15CH

Pulsatilla pratensis 15CH

Sepia officinalis 15CH

Silica terra 15CH

Sulphur 15CH

The constitutional remedy was chosen for each patient according to Allen (1978), using keynotes and characteristic symptoms.

3.3.1 Object of the study

The object of the study was to determine whether there was significant changes, in the subjective and objective symptoms, after homoeopathic medicines were taken by the patients. This was done to evaluate homoeopathic medicines as an adjunct in asthma management.

3.3.2 Allocation of Subjects

A system was used whereby the homoeopathic dispenser wrote a random sequence of 4 letters (2xP's and 2xT's) on a 10 pieces of paper. For example: TPTP, TTPP, PPTT, PTPT, etc.

T = Treatment Group and P = the placebo group. Each piece of paper was then folded in such a way that the letters could not be seen. The

folded papers were then shuffled. Nine of the papers (36 letters) were drawn in turn. The sequence of the letters on each slip was made into a list. The patients were then allocated to the next available T or P in the sequence.

For example:

No.	T/P	Patient's Name
1	T	Patient 1
2	P	Patient 2
3	T	Patient 3
4	P	Patient 4
5	T	Patient 5
6	T	Patient 6
7	P	Patient 7
8	P	Patient 8

3.3.3 Inclusion and exclusion criteria

Parameters were set so that the variables were minimised as far as possible:

- Patients who were pregnant or who became pregnant during the trial were excluded from the study. Besides the ethical issues involved, it was found that women pregnant with girls were more likely to experience an exacerbation of their asthma, during their pregnancy (Van Schoor, 1999a).

- Patients who used any other medication besides a metered salbutamol aerosol inhaler were excluded from the study.
- Only patients who were between, and inclusive, of the ages of 16 and 36years of age were included in this study.
- Patients had to have been medically diagnosed as having atopic asthma.
- Patients suffering with chronic bronchitis and/or emphysema were excluded from the study.
- Patients using corticosteroids were excluded from the study. Some homoeopaths do treat patients using oral corticosteroids. The corsticisteroids may mask the asthmatic symptoms, making remedy selection more difficult. (Kayne, 1997.)
- Smokers were excluded from this study.

3.3.4 Preparation of Homoeopathic Remedies

Natura Laboratory (Pretoria) supplied the base substances. A qualified homoeopathic pharmacist, Dr Peter Frazer, did all required preparation of the remedies and placebo at Technikon Natal. Mrs Nola Frazer, who

is also a qualified homoeopathic pharmacist, dispensed the medication and placebo.

3.3.4.1 Placebo Pillules

Unmedicated pillules were impregnated with Alcohol 70% at a rate of 1% v/v, to negate effects due to the alcohol used in the preparation of the remedies. This process was done in three stages. A third of the alcohol was slowly dropped onto the pillules whilst the pillules were continuously swirled in a beaker. The pillules were swirled in the beaker until they were dry. This process was repeated three times.

3.3.4.2 House Dust Allergen 30CH (Allergode)

Asthmatic children tend to be more allergic compared to the non-asthmatic population of children. Pollens, house dust, house dust mites, and animal danders can trigger an asthma attack. (Edinburg, 1998.) Besides these triggers vacuum cleaner dust contains other triggers, which the asthmatics inhale or come into contact with. It is for this reason that vacuum cleaner dust was used to make up the allergode. Six samples of vacuum cleaner dust were obtained from six locations in KwaZulu-Natal, South Africa. These locations were: Sheffield Beach,

Munster, Amanzimtoti, Westville, Summerveld, Pietermaritzburg and Durban. The sites of collections were chosen to represent a number of areas in Kwa-Zulu Natal, with Durban being the epicentre. Ten grams of vacuum cleaner debris from each location was used. A mixture of both coarse and fine material was used in each sample. Some mould from a bathroom ceiling was added to the Summerveld sample. The samples were then mixed and a pair of scissors was used to cut all the fibres as finely as possible. This mixture was then dry ground in a mortar for 1 hour with a pestle. The resultant ground material was then sifted through a No. 250 wire mesh sieve.

The resulting powder was then used to prepare the *House Dust Allergen* 30CH according to the German Homoeopathic Pharmacopoeia (English translation: 1991). The 30CH potency was made up using alcohol 70% v/v, to facilitate pillule impregnation and drying.

3.3.4.3 The 15CH Remedies

The constitutional remedies and the *Lung Histamine* 15CH were obtained from Natura Laboratories, Pretoria. The remedies were made according to the German Homoeopathic Pharmacopoeia (English translation: 1991). The laboratory made the final potencies in alcohol

(70%). The liquid remedies were then used to impregnate the unmedicated pillules at a rate of 1% v/v. This was done in three stages, as described for the placebo pillules.

3.4 Interventions

For the initial 2 weeks a "dry" run was done to determine a base line for readings. For the next eight weeks the treatment group received medicated pillules according to the prescribed regimen. The placebo group received unmedicated lactose pillules during this time. These were visually identical and tasted exactly like the medicated pillules.

3.4.1. Procedures in the execution of the study.

1. During the initial interview the applicants were screened for suitability of this study. A consent form (Appendix B) was signed if the patient was deemed to be suitable for this study in terms of the inclusion and exclusion criteria.
2. The object and procedure of the study was explained to each applicant.

3. A medical and homoeopathic case history was taken. Only key-notes were used so that repertorization was simplified.

4. It was explained to the patient how the peak flow meters were to be used and how the record charts (Appendix C) were to be completed. The patients were also instructed on the proper use of their metered dose salbutamol asthma pumps. (Appendix F)

5. Each patient was issued with an Assess peak expiratory flow meter, which was manufactured by Boehringer Ingelheim. The patients were then showed how to use the peak expiratiry flow meter and how to record the results.

6. For the initial two weeks ("Dry" run):

   i. Both the placebo and treatment groups were given blank pillules by the homoeopathic pharmacist.

   ii. The patients had to take the medication as directed and keep daily records as directed. (Appendix E)

7. After the initial two weeks:

   i. All questions and queries, which the patients had, were addressed.

   ii. The record cards (Appendix C1) were checked to ensure that the patients completed them correctly.

iii. The completed record sheets were then retained by the researcher and new record sheets (Appendix C2) for the next four weeks were issued to the patients.

iv. The patients were given an Asthma Quality of Life Questionnaire (Appendix D) to complete in the presence of the researcher. The homoeopathic pharmacist issued the patient with medicines. Those in the placebo group were issued blank pillules, which looked identical to the medicated pillules. Those in treatment group received medicated pillules.

8. After the initial 4 weeks of the trial:

i. The record sheets (Appendix 2C) were collected and checked.

ii. The patients' prescriptions were refilled.

iii. New record sheets (Appendix C3) for the final 4 weeks of the trial were issued to the patients.

9. After the final 4 weeks:

i. The final record sheet was collected from the patient.

ii. The patients completed the second Asthma Quality of Life Questionnaire (Appendix D).

3.5 *Statistical analysis*

A 7-day arithmetic mean was determined and used, for the daily peak flow readings and the pump usage scores, to facilitate data analysis.

Non-parametric tests were used in cases where the data was of a categorical nature. The Mann-Whitney U-test was used for inter-group comparisons between the treatment and placebo groups. While the Wilcoxon Signed Rank test was used for intra-group comparisons. (Daniel, 1987: 31-37.) Friedman's Non-parametric test for analysis of variance (ANOVA) was used for intra-group analysis of data relating to pump usage, asthma severity and peak expiratory flow readings.

The t-test was used where the data was continuous in nature. It is assumed that the variable had a normal distribution. (Reid and Boore, 1987: 76) The two-sample unpaired t-test was used for inter-group analysis of PEF data.

The data obtained from the questionnaires and record sheets were analysed using the SPSS Version 9.0 statistical analysis programme. The level of significance was set at 5% (α=0.05).

Chapter 4: Results

4.1 Introduction

This chapter summarises the objective and subjective data obtained for the study. The processed and analysed data represent the following measurement criteria:

- Morning Peak Expiratory Flow Readings
- Salbutamol inhaler usage
- Asthma Severity Score
- Asthma Quality of Life Scores

The level of significance was set at 5% (α=0.05).

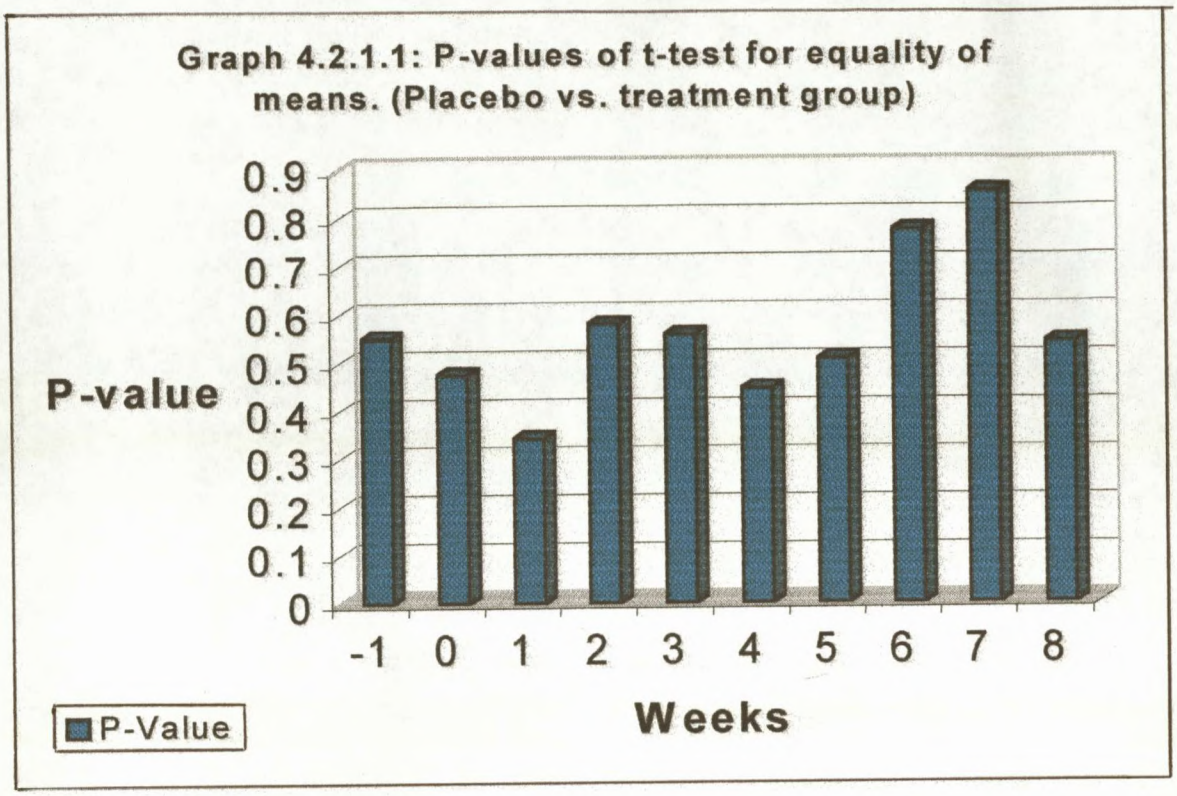
4.2 Results

4.2.1 Morning Peak Expiratory Flow Data

4.2.1.1 Inter-group comparison of PEF data.

Week	P-Value
-1	0.552
0	0.476
1	0.343
2	0.581
3	0.559
4	0.446
5	0.507
6	0.775
7	0.855
8	0.543

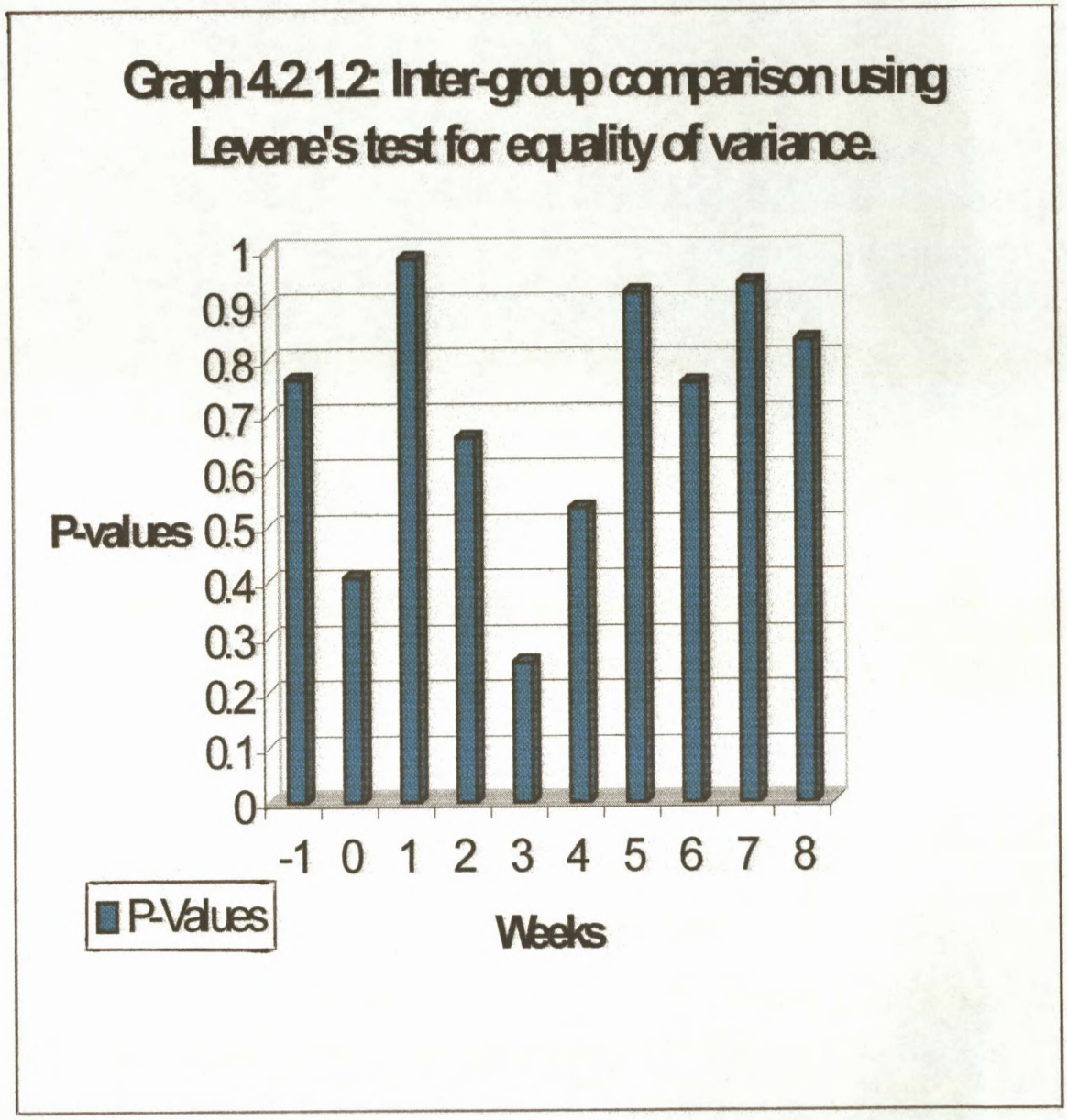
Table 4.2.1.1: Inter-group P-values for t-test (Equality of means).



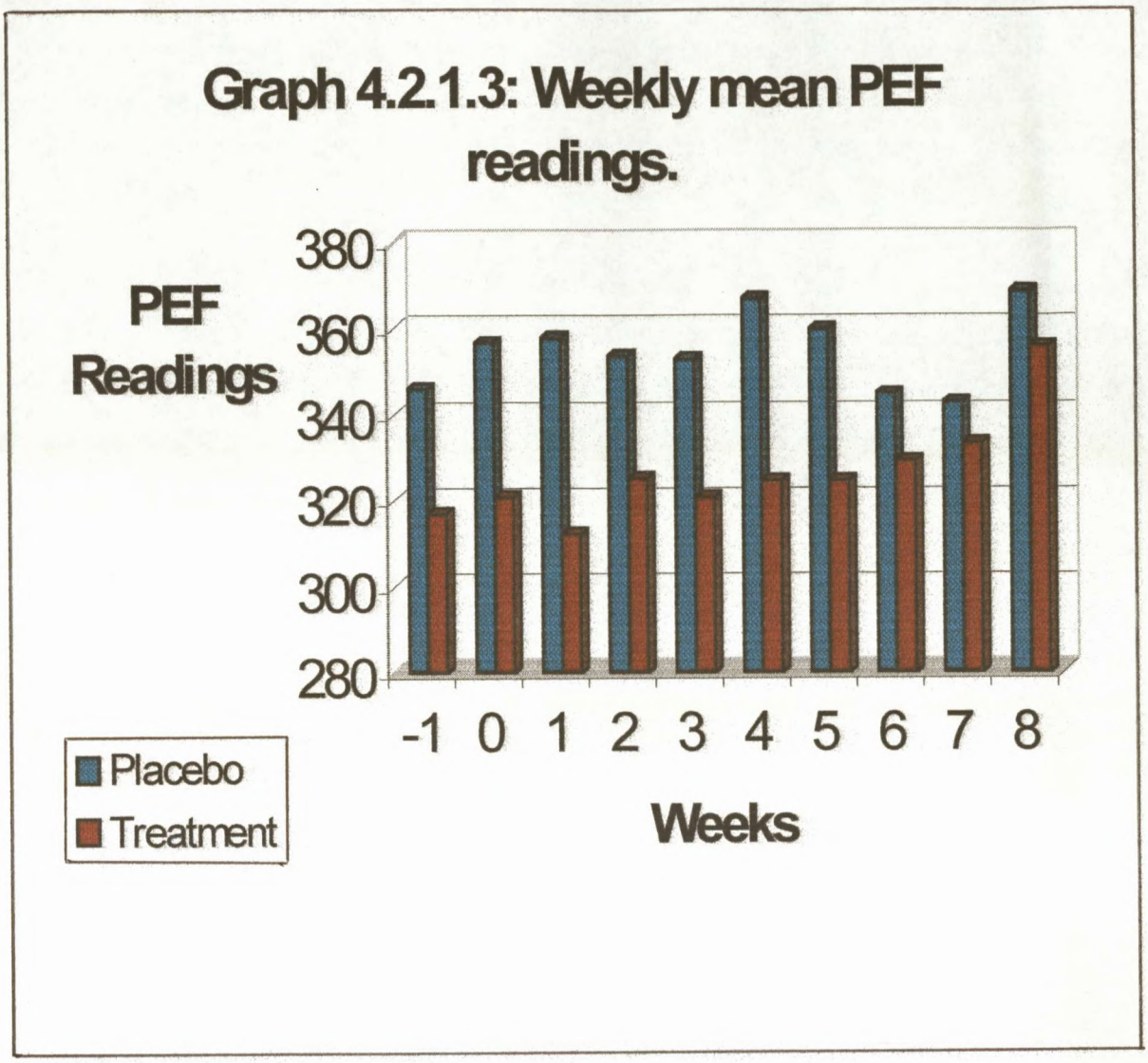
Using the t-test for Equality of Means it was found that in all cases the P-value was greater than the level of significance (α=0.05). Hence, it was concluded that there was no significant difference between the means of the placebo and treatment groups in terms of Morning Peak Expiratory Flow data.

Week	P-value
-1	0.776
0	0.406
1	0.984
2	0.660
3	0.255
4	0.532
5	0.923
6	0.759
7	0.939
8	0.835

Table 4.2.1.2: P-values determined by Levene's test for equality of variance between the two groups.



Using Levene's test for Equality of Variances, all the P-values were found to be greater than (α=0.05). Hence, the null hypothesis was accepted. It was concluded that no significant difference was found between the placebo and test group, in terms of mean PEF data.



The graph (4.2.1.3) shows that the seven-day mean PEF readings in the placebo group were in a relatively narrow band. The mean PEF readings for the treatment group showed a rising tendency as the study progressed. The initial wide disparity between the mean readings of the placebo and treatment groups may have been due to chance and the small sample size used.

4.2.1.2 Intra-group comparisons of PEF data.

4.2.1.2.i Analytical comparison within the placebo group

(Univariate parametric ANOVA test)

The P-value was found to be 0.741. This value is greater than the level of significance (α=0.05). Therefore, it is concluded that there is no significant difference in the placebo group, between the beginning and the end of the trial for the PEF data.

4.2.1.2.ii Analytical comparison within the treatment group.

(Univariate parametric ANOVA test)

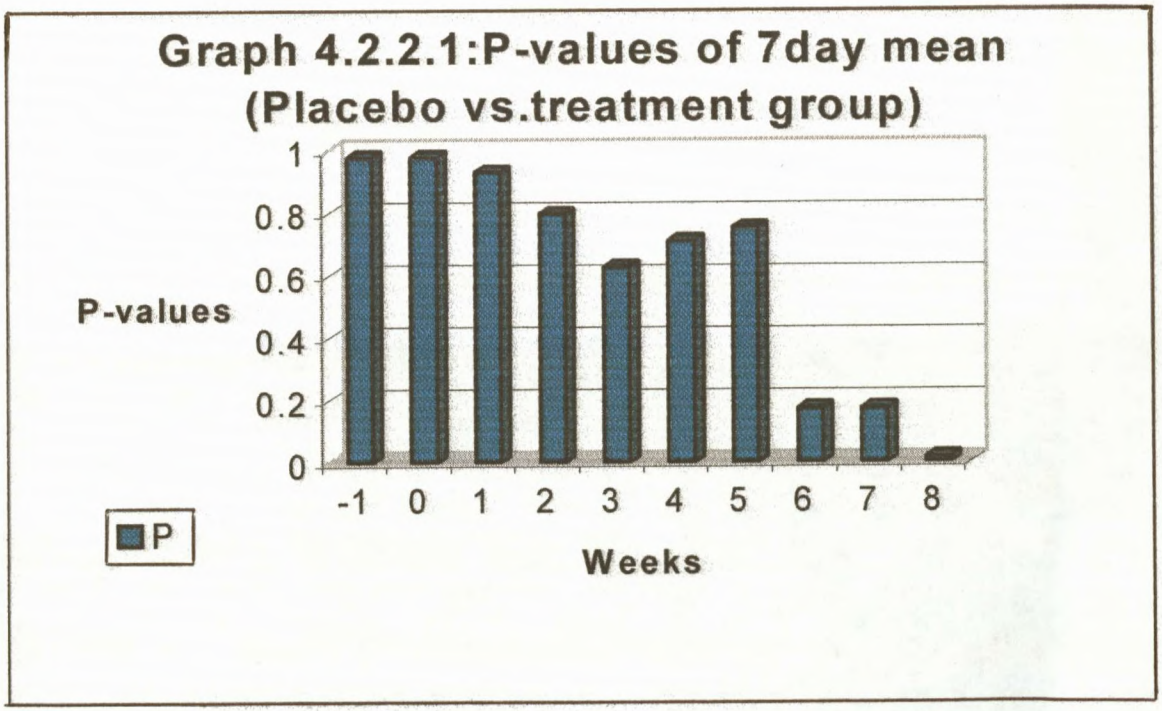
The P-value was found to be 0.971. This value is greater than the level of significance (α=0.05). Therefore, it is also concluded that there is no significant difference in the treatment group, between the beginning and the end of the trial for the PEF data.

4.2.2 Asthma Pump Usage

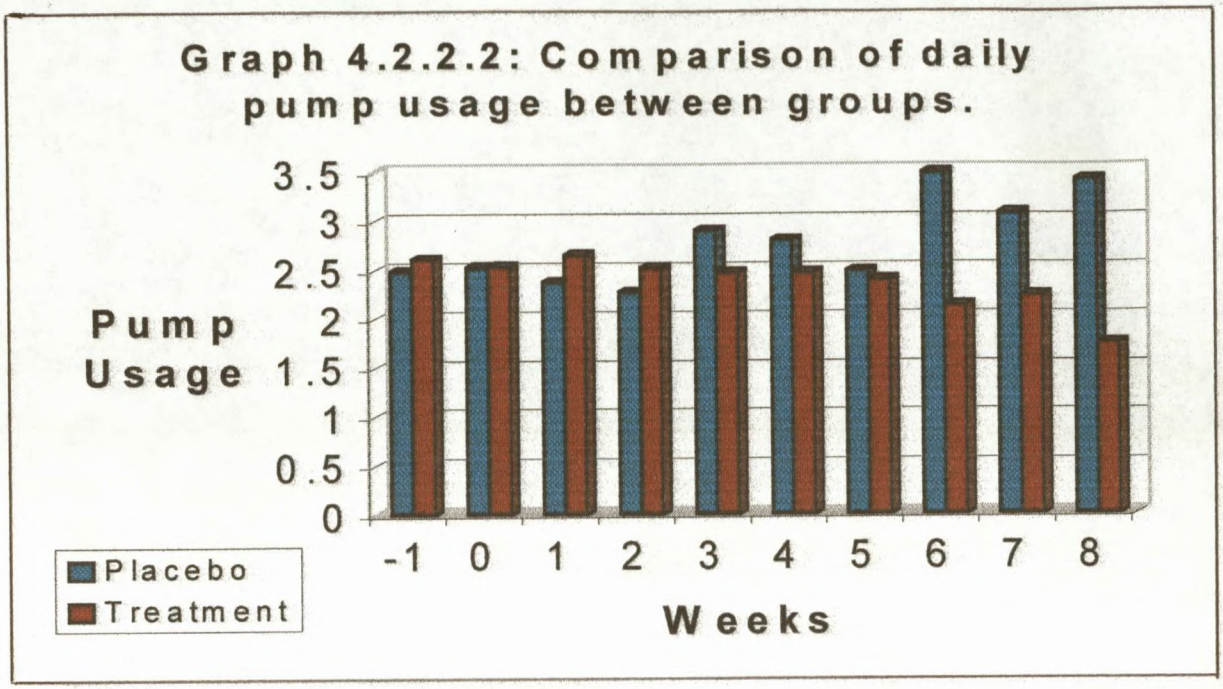
4.2.2.1 Inter-group comparisons of Asthma Pump Usage data.

Week Number	P-Values
-1	.977
0	.977
1	.931
2	.796
3	.625
4	.709
5	.752
6	.172
7	.172
8	.016

Table 4.2.2.1: P-values of seven-day arithmetic mean comparing placebo to treatment group. It is shown that only in the final week of the study was there a statistically significant difference between the 7-day mean in Asthma Pump Usage between the placebo and the treatment groups. (Whitney-Mann U-test)



Graph 4.2.2.1: P-values of 7-day mean of daily Asthma Pump Usage. (Placebo vs treatment group.)



From the previous table and graph (4.2.2.1) it can be seen that in nine of the ten treatment groups the P-value was greater than (α=0.05). Only in the observation at the end of the trial was the P-value (P=0.016) less than (α=0.05). Hence, only in the last observation was the null hypothesis rejected. It was concluded that there was only a significant difference between the placebo and the treatment group at the end of the study.

The general trend in pump usage in the placebo group was increasing. In the case of the treatment group this trend was decreasing. This indicates that the placebo group tended to use their asthma pumps more frequently as the study progressed. The opposite was true for the treatment group. Their pump usage decreased as the study progressed.

4.2.2.2 Intra group comparisons of Asthma Pump Usage data.

4.2.2.2.i Analytical comparison within the placebo group.

(Friedman's non-parametric ANOVA test).

The P-value was 0,385. At the level of significance (α=0.05), P > α, hence the null hypothesis was accepted. There was no significant difference in the frequency with which the salbutamol inhaler was activated before or after intervention in the placebo group.

4.2.2.2.ii Analytical comparison within the treatment group.

(Friedman's non-parametric ANOVA test).

The P-value was 0.287. At the level of significance (α=0.05), P > α, hence the null hypothesis is accepted. There was no significant difference in the frequency of salbutamol inhaler usage before and after intervention in the treatment group.

4.2.3 Asthma Severity Score

4.2.3.1 Inter-group comparisons of asthma severity.

Observation	P-Values
At the start of the 'dry' run.	0.546
At the beginning of the trial.	0.977
At the half way stage of the trial.	0.625
At the end of the trial.	0.019

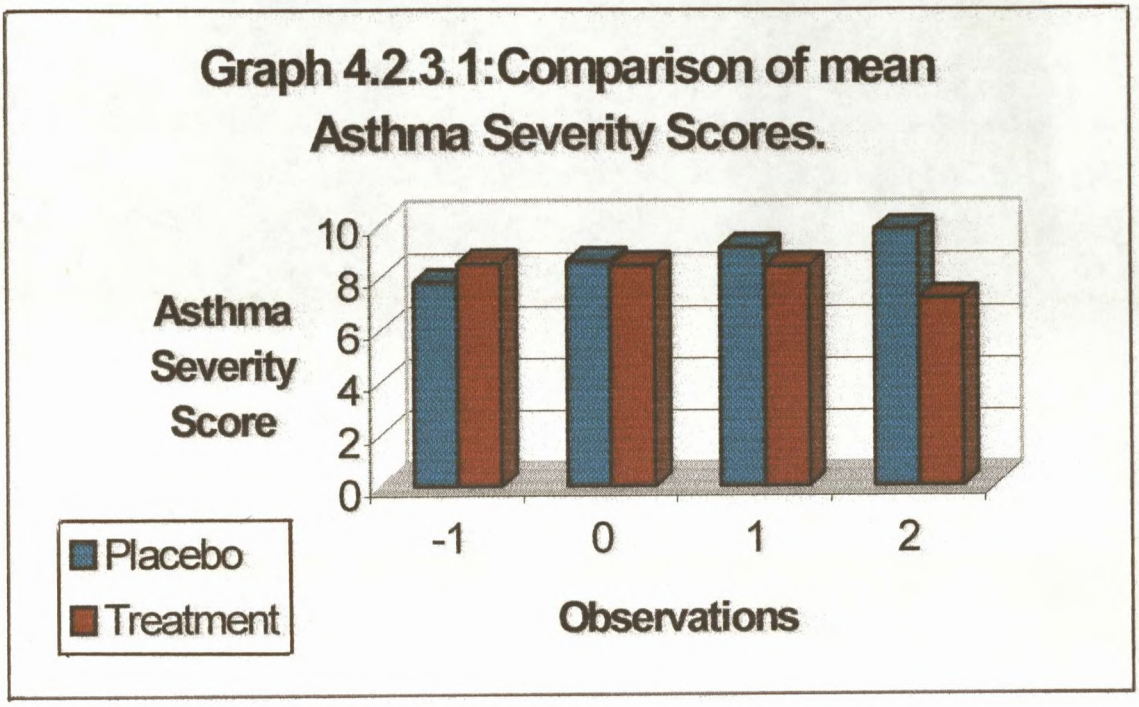
Table 4.2.3.1 P-values for asthma severity at each observation using. (Mann-Whitney U-test.)

The data was categorical in nature. The data comparison between the placebo and treatment groups was analysed using the Mann-Whitney U-test.

Only at the end of the trial was the P-value (0.019) less than the level of significance (α=0.05). In this case the null hypothesis is rejected. It was concluded that there was a significant difference between the Asthma Severity Scores between the placebo and treatment group.

	-1	0	1	2
Placebo	7.8	8.6	9.1	9.8
Treatment	8.5	8.429	8.4	7.143

Table 4.2.3.2: Mean Asthma Severity Scores at each observation.



In the placebo group the mean Asthma Severity Score had a generally increasing trend. The trend for the treatment group was generally decreasing. It was concluded that, asthma symptoms in the placebo group deteriorated as the trial proceeded. It was also concluded that asthma symptoms in the treatment group improved as the study progressed. The difference between the placebo and treatment group was wide enough to conclude that the difference was significant (P=0.019).

4.2.3.2 Intra group comparisons of asthma severity.

4.2.3.2.i Analytical comparison within the placebo group.

The data was categorical in nature. The data was analysed using the Friedman's non-parametric ANOVA test.

The P-value was found to be 0.011. Hence, there was a significant difference in the placebo group between the beginning and the end of the trial, in terms of mean Asthma Severity Scores. From the graph it can be seen that the placebo group experienced deteriorating symptoms as the trial progressed.

4.2.3.2.ii Analytical comparison within the treatment group.

The data was categorical in nature. The data was analysed using the Friedman's non-parametric ANOVA test.

Here the P-value was found to be 0.100. Hence, there is not a significant difference in the treatment group between the beginning and the end of the trial, in terms of mean Asthma Severity Score.

4.2.4 Asthma Quality of Life Questionnaire (AQLQ) – Individual questions.

4.2.4.1 Inter group comparisons for individual questions of the AQLQ.

Question	P-value
Q11A	0.341
Q11B	0.508
Q21A	0.371
Q21B	0.796
Q31A	0.108
Q31B	0.931
Q41A	0.841
Q41B	0.585
Q51A	0.259
Q51B	0.886
Q61A	0.192
Q61B	0.841
Q71A	0.172
Q71B	0.841
Q81A	0.841
Q81B	0.401
Q91A	0.709
Q91B	0.403
Q101A	0.841
Q101B	0.259

Question	P-value
Q111A	0.931
Q111B	0.212
Q121A	0.666
Q121B	0.437
Q131A	0.437
Q131B	0.312
Q141A	0.796
Q141B	0.341
Q151A	0.096
Q151B	0.259
Q161A	0.259
Q161B	0.371
Q171A	0.585
Q171B	0.546
Q181A	0.235
Q181B	0.625
Q191A	0.472
Q191B	0.546
Q201A	0.472
Q201B	0.312

A= First Questionnaire
B= Second Questionnaire

Table 4.2.4.1: P-values as calculated by Mann-Whitney U-test for AQLQ scores.

In all the above cases the P-value was greater than the level of significance (0.05). It was concluded that there was no significant difference between the placebo and treatment group in all the questions, in terms of mean AQLQ scores.

4.2.4.2 Intra group comparisons for individual questions of the AQLQ.

4.2.4.2.i Analytical comparison within the placebo group.

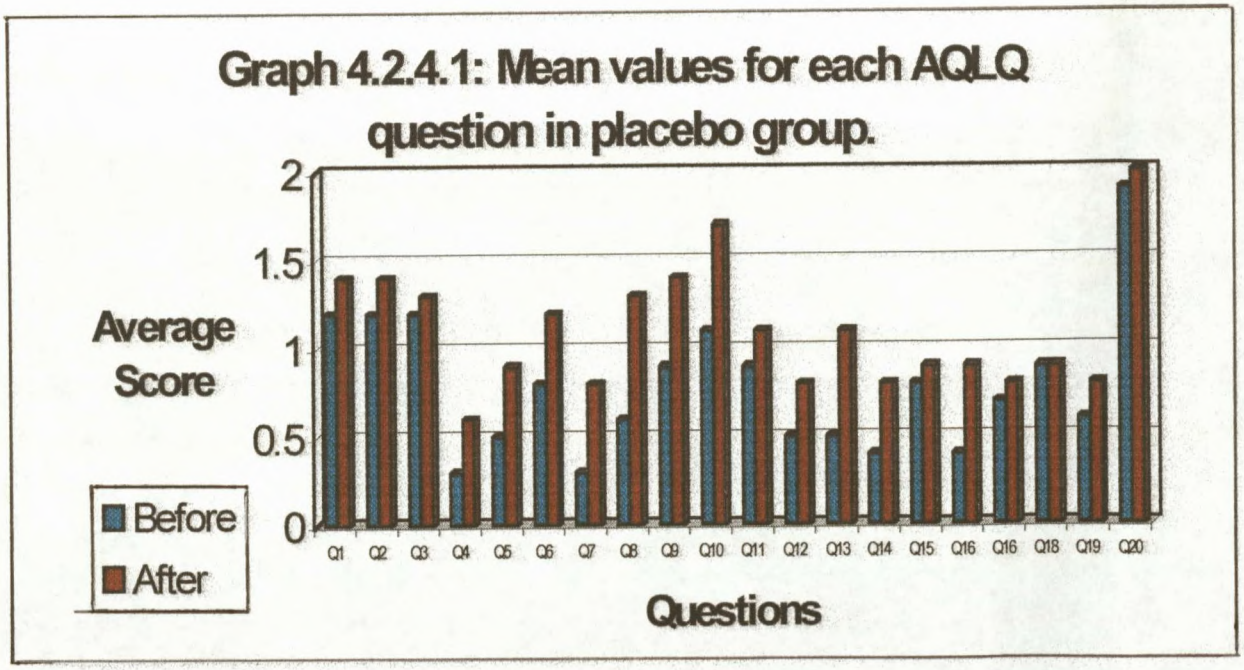
(Wilcoxon's Signed Ranks test)

Question: Placebo	P-value
Q11B-Q11A	0.414
Q21B-Q21A	0.480
Q31B-Q31A	0.705
Q41B-Q41A	0.461
Q51B-Q51A	0.194
Q61B-Q61A	0.234
Q71B-Q71A	0.059
Q81B-Q81A	0.059
Q91B-Q91A	0.238
Q101B-Q101A	0.119

Question: Placebo	P-value
Q111B-Q111A	0.577
Q121B-Q121A	0.450
Q131B-Q131A	0.167
Q141B-Q141A	0.157
Q151B-Q151A	0.705
Q161B-Q161A	0.096
Q171B-Q171A	0.564
Q181B-Q181A	1.000
Q191B-Q191A	0.480
Q201B-Q201A	0.783

Table 4.2.4.2: P-values for each question as determined by Wilcoxon's Signed Ranks test. (Placebo Group)

In this case calculated P-values for all the questions show that there is no significant difference before and after intervention within the placebo group.



From the preceding graph (4.2.4.1) it can be seen that in the placebo group, there was a tendency for the mean Asthma Severity Scores to be higher for the second questionnaire. It was concluded that the subjective perceptions of the patients deteriorated as the trial proceeded.

4.2.4.2.ii Analytical comparison within the treatment group. (Wilcoxon's sign ranked test)

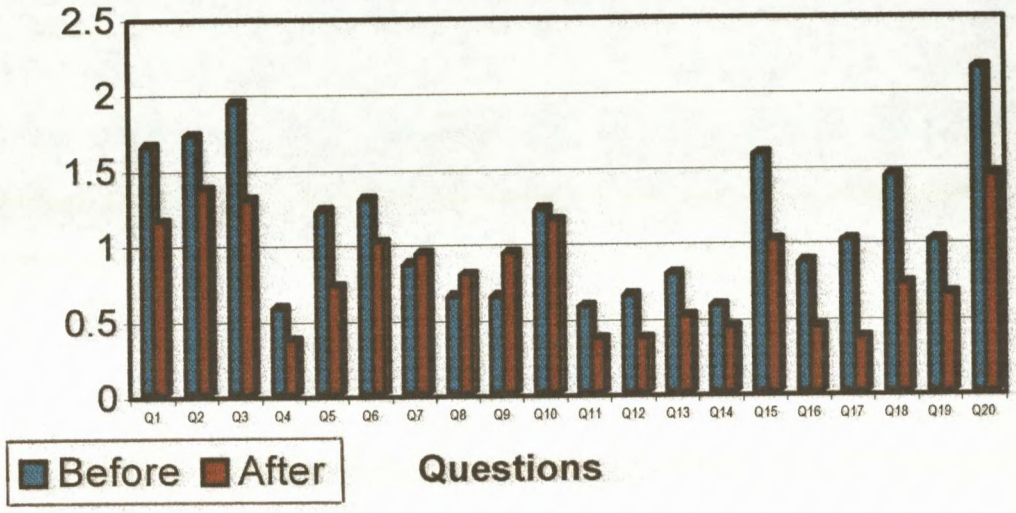
Question: Treatment	P-value
Q12B-Q12A	0.083
Q22B-Q22A	0.059
Q32B-Q32A	0.021
Q42B-Q42A	0.450
Q52B-Q52A	0.085
Q62B-Q62A	0.271
Q72B-Q72A	0.832
Q82B-Q82A	0.726
Q92B-Q92A	0.380
Q102B-Q102A	0.926

Question: Treatment	P-value
Q112B-Q112A	0.518
Q122B-Q122A	0.157
Q132B-Q132A	0.157
Q142B-Q142A	0.414
Q152B-Q152A	0.063
Q162B-Q162A	0.131
Q172B-Q172A	0.098
Q182B-Q182A	0.026
Q192B-Q192A	0.257
Q202B-Q202A	0.046

Table 4.2.4.3: P-values for each question as determined by Wilcoxon's Signed Ranks test. (Treatment Group)

In seventeen of the twenty questions the P-value was greater that the level of significance (α=0.05). A significant difference was seen for the treatment group in Question 3 (P=0.021), Question 18 (P=0.026) and Question 20 (P=0.046).

Graph 4.2.4.2 : Mean values for each AQLQ question in treatment group.



In the majority of cases the patients in the treatment group scored less when they completed the questionnaire for the second time. It was concluded that the treatment group's perception of their quality of life had generally improved during the trial. In three of the questions, however, patients scored higher in the second questionnaire. These three questions (Q7, Q8 and Q9) form part of the "Mood Disturbance" sub-score category. These three questions indicated that the patients in the treatment group felt that their sleep (P=0.832), depression (P=0.726) and frustration (P=0.380) levels had deteriorated. All three of the P-values were greater than the level of

significance (α=0.05). The deterioration in these 3 symptoms was not statistically significant.

4.2.5 Total AQLQ score.

The sum of the values for each of the questions in the Asthma Quality of Life Questionnaire was determined to yield a value out of a possible eighty. This value was recorded and used in the analysis of this data.

4.2.5.1 Inter group comparisons of total AQLQ scores.

The Mann-Whitney test was used to analyse the data between the placebo and the treatment groups. The P-value was found to be 0.752 when the values for the placebo group and the treatment were compared for the first questionnaire. The P-value was found to be 0.312 when the data from the second AQLQ between the placebo and treatment group were compared. The P-value for the second questionnaire was smaller, implying a larger difference in the scores. In both cases the P-value was greater than the level of significance (α=0.05), hence it was concluded that there was no significant difference between the scores achieved by each group in the first and second questionnaire.

4.2.5.2 Intra group comparisons of total AQLQ scores.

4.2.5.2.i Analytical comparison of total AQLQ scores within the placebo group.

Using Wilcoxon's Signed Ranks test to compare scores achieved by the placebo group in the first and second questionnaire, the P-value was found to be 0.185.

Hence, it was concluded that there was no significant difference in the scores achieved before intervention and after intervention, at the 5% level of significance.

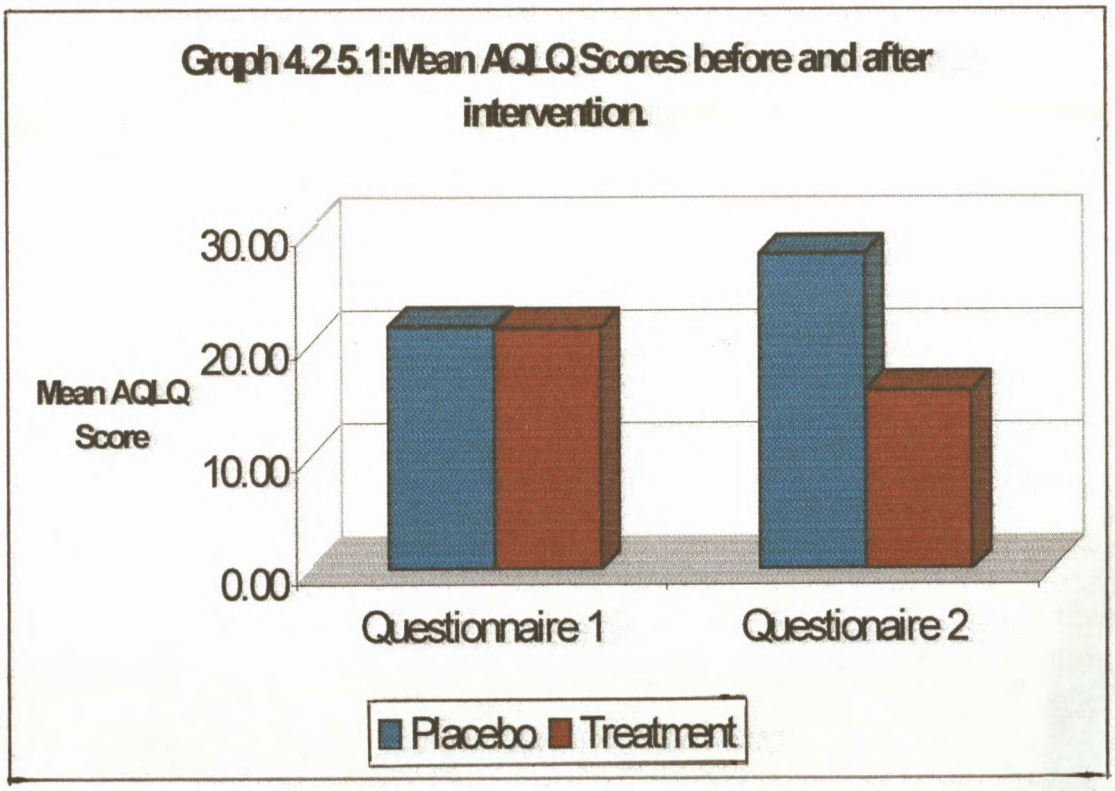
4.2.5.2.ii Analytical comparison of total AQLQ scores within the treatment group.

Using Wilcoxon's Signed Ranks test to compare the scores achieved by the treatment group between the first and second questionnaire, the P-value was found to be 0.064. ($P>\alpha$)

Hence, it was concluded that there was no significant difference in the scores achieved before intervention and after intervention, at the 5% level of significance.

	Questionnaire 1	Questionnaire 2
Placebo	21.60	28.00
Treatment	21.43	15.86

Table 4.2.5.1: Inter-group comparison of mean total AQLQ scores before and after intervention.



The above graph shows that the mean scores achieved by the two groups for the first questionnaire were similar. In the second questionnaire the score achieved by the placebo group had increased, this indicates that the patients in this group perceived that their quality

of life had deteriorated. The mean total AQLQ score had decreased in the treatment group. This showed that the patients in the treatment group perceived that their quality of life had improved after homoeopathic intervention. This difference between the placebo group and the treatment group at the end of the study was not statistically significant (P=0.064).

4.2.6 Patients lost to the study

Eight out of the 32 patients initially recruited did not complete the study. In the placebo group six patients dropped out. Of these, one patient did not have symptoms severe enough to partake in the study. One patient failed to complete his record sheet satisfactorily. One patient dropped out, because of nausea and other side effects. Three patients "lost" their record cards.

In the treatment group two patients dropped out. One patient had to resort to using cortisone and sodium cromoglycate for her asthmatic condition. During the trial one patient found that she was pregnant. It was decided, for ethical reasons, that she not be allowed to continue with the study.

Patients lost to the study were not replaced. Environmental conditions had to be kept as constant as possible for all participants in the trial. Variables such

as pollen counts, atmospheric pollution and weather conditions would not have been constant for new recruits to the trial. It was imperative that all participants start and end the trial at the same time.

4.3 Conclusion

The majority of the calculated P-values were greater than the 5% level of significance. As the study progressed the P-values were seen to decrease, implying an increase in statistical significance as the trial progressed. At the end of the study there was a significant difference in the asthma severity score (P=0.019) when the groups were compared. Intra-group comparison for the Asthma Severity Score showed an improvement for the treatment group (P=0.100). The placebo group showed a significant deterioration in Asthma Severity Score (0.011) at the end of the study. In three of the twenty questions of the AQLQ there was a significant difference within the treatment group at a 5% significance level. From the graphs it was seen that in all cases there was deterioration in both the subjective and objective results in the placebo group. On the other hand, there was an improvement in the results of the treatment group after homoeopathic intervention. There was a general trend of improvement as the study progressed in the 7-day mean PEF readings, the pump usage scores, the asthma severity scores, and the AQLQ scores.

Chapter 5: Discussion

The results obtained from this research, indicate that there was a measurable improvement in patients using the studied homoeopathic regimen. During the study period subjective and objective symptoms in the placebo group generally deteriorated. In the case of the treatment group, there was generally an improvement.

After the first week of medication the treatment group showed a dip in their mean PEF readings. This may have been as a result of a homoeopathic aggravation. According to Weiner (1989: 64) this aggravation occurs a few days after a homoeopathic remedy is given for a chronic condition, and this is an excellent prognostic sign. After this initial dip there was amelioration, followed by a second milder aggravation. Hahnemann (1983: 54) observed this phenomenon when remedies were prescribed, based only on symptoms. After the second dip there was a steady improvement of the PEF readings as the trial progressed. The results were not statistically significant. These results however, do invite further investigation.

Inter-group comparisons do show a steady decrease in P-values for asthma usage scores as the study progressed. There was a significant difference (P=0.016) in asthma pump usage at the end of the study. While the pump usage tended to increase for the placebo group, it decreased for the treatment group. This suggests that the combination of homoeopathic remedies used in the study was effective in reducing asthma pump usage.

Inter-group comparison showed that at the end of the trial there was a significant difference (P=0.019) in the asthma severity scores. As the trial progressed there was a significant deterioration (P=0.011) in the asthma severity score for the placebo group. In the case of the treatment group the asthma severity score steadily improved (decreased) as the study progressed (P=0.100). The greatest difference between the scores was at the end of the trial.

In the treatment group there was a significant improvement in the perceptions of the patients, for three of the twenty questions in the AQLQ. These questions referred to chest tightness (P=0.021), anxiety concerning health because of asthma (P=0.026) and dependency on asthma sprays (P=0.046). Intra-group comparison indicated a slight improvement of total AQLQ scores (P=0.064).

There were significant improvements in the data concerning PEF readings, asthma pump usage, asthma severity scores and in some questions used in the AQLQ. It can be seen that there is scope for using the experimental combination of homoeopathic medicines as an adjunct to asthma management. This study cannot be extrapolated to include the recommendation of decreasing corticosteroid inhaler usage. Bronchial inflammation, an important factor in asthma management, was not monitored.

One of the main problems encountered in this study was that record keeping was found to be time consuming and tedious. Initially the patients were required to monitor PEF readings in the morning and at bedtime. They also had to record data on the severity of their wheezing both during the day and at night, and how their asthma limited their activity. A comment sheet was also provided so that the patients could record any notable comments: emotional upsets, unusual signs and symptoms, being away from home, etc. During the "dry" run it was reported to the researcher that this was too arduous. A few of the patients even threatened to withdraw from the study.

The patients were required to start the study at the same time to minimise variations in pollen counts, weather, and other factors, which could

influence asthma severity. In order to prevent patient withdrawal and ultimately, abortion of this study, it was decided to reduce the record keeping. It was then decided to limit the record keeping to morning PEF readings, daily asthma pump usage, and asthma severity scores on four designated Sundays. The AQLQ was completed at the beginning and at the end of the trial. Even this reduced data collection protocol was too tedious for some patients, resulting in "lost" record sheets.

Spirometry might be considered for lung function monitoring. However, this also has its disadvantages. If the tests are only done at the beginning and at the end of the study, one has to deal with too many variables. These variables include; the emotional state of the patient at the time of the test, air pollution, exertion prior to the test appointment, etc. Having the patients do more frequent tests may also lead to more resistance, because of the time required. Patients would have to take time off to have the spirometry test done. Variability of severity is one of the hallmarks of asthma. The symptoms and bronchial diameters vary numerous times a day. Having too few measurements would result in a distorted outcome.

Chapter 6: Conclusion and recommendations

The facts indicate that the recommended homoeopathic regimen was effective in reducing asthma severity and improving quality of life perceptions.

Pump usage at the end of the study showed that the treatment group used their metered asthma pumps significantly less than the placebo group (P=0.016). Inter-group comparison of asthma severity scores were found to be lower for the treatment group (P=0.019). Intra-group comparison of the treatment group revealed that there was an improvement in the perceptions of the patients concerning chest tightness (P=0.021), anxieties regarding health (P=0.026) and asthma pump dependency (P=0.046).

I recommend that this study be used as a base for further research into the homoeopathic treatment of asthma. The study needs to be extended in both duration and sample size. Both these recommendations may reveal greater statistical significance. Increasing the sample size will also help to eliminate the initial disparity of the collected data. It is also necessary to extend the length of the study to see whether the

improvements continue increasing and to what extent. Another factor to look at, is whether this improvement is sustainable, or will there be a deterioration, due to a homoeopathic *proving* taking place. Research involving different potencies, dosage frequencies or different homoeopathic approaches and prescriptions could also be considered.

Other mediators, like the leukotrienes, which are involved in the pathophysiology of asthma, need to be considered. Homoeopathically potentised leukotrienes may be useful in countering the effects of physiological leukotrienes.

The ultimate aim of this study is to find a way of asthma management, which is safe, effective and cost-effective. It may be possible that, using a larger sample size, the most commonly required constitutional remedies may be identified. Then using the keynotes of a remedy to guide his choice, the patient can choose one that best suits him. This allows the patient to self-prescribe the homoeopathic regimen.

This homoeopathic regimen may allow patients to reduce the use of their bronchodilator inhalers and improve their quality of life. At this stage it is envisaged that the patients continue to use their asthma pumps

on a "when necessary" basis, in addition to their homoeopathic medicines. A stage may be reached where the patient may become asymptomatic, and the pump not required. The patient will have to monitor PEF readings to gauge the severity of bronchial narrowing. This is also important, so that if a homoeopathic proving is experienced, the necessary steps can be taken.

This regimen, can at this stage only be recommended for mild asthma, where corticosteroids are not required for asthma management. The effects of corticosteroids were not studied in this trial. A further study into the effects of homoeopathic medicines on bronchial inflammation is recommended.

It must also be remembered that this regimen was designed with long term asthma management in mind. Its use in aborting acute asthmatic attacks is, therefore not recommended.

When data is analysed statistically, we must determine whether there are significant differences after intervention. The aim of determining significance is to minimise changes and conclusions due to chance. However, when these changes are statistically insignificant, but show a definite trend, they are worth considering for further study.

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Appendices

Appendix A: Poster used for recruitment of patients.

Appendix B: Informed consent form.

Appendix C:

Appendix C1: Record sheet (Two week "dry" run.)

Appendix C2: Record sheet (First 4 weeks of trial.)

Appendix C3: Record sheet (Second 4 weeks of trial.)

Appendix D: Asthma Quality of Life Questionnaire.

Appendix E: Instructions for completion of record sheet.

Appendix F: Instructions for the use of asthma pump.

Appendix G: Frequency of remedies used in each group.

Appendix A

ASTHMA

IF YOU USE ONLY VENTOLIN OR VENTEZE PUMPS TO CONTROL YOUR ASTHMA AND ARE BETWEEN 16 AND 36 YEARS OLD.....

WE NEED YOU FOR RESEARCH

TO DEVELOP AN ALTERNATIVE MEANS OF ASTHMA MANAGEMENT

PLEASE CONTACT:

Lawrence Tak (Dip Pharm M.P.S.)
Department of Homoeopathy
Technikon Natal
Berea, Durban,

Tel: 225-2041 OR 225-2542

Appendix B

Asthma Research Consent Form

Thank you for participating in this research study. Our aim is to enhance the knowledge we have on asthma and its management.

The duration of this study will be two and a half months. The double blind trial protocol will be used, so that bias may be eliminated as much as possible.

It will be expected that the patient keep accurate records for the duration of the study.

In emergencies other medications, besides your Ventolin or Venteze (salbutamol) aerosol pumps will be permitted. These must, however, be kept to a minimum. The dosage and duration of any additional medication must be meticulously recorded.

Smokers, patients with any conditions, which may have a bearing on the severity of asthma, and pregnant patients will be excluded from this study.

The peak flow meters and records used in this study will remain the property of Technikon Natal.

Technikon Natal, the staff and the researcher cannot be held responsible for any adverse occurences, which may arise as a result of this study.

Patient:..... Signature.....

Date:.....

Witness:..... Signature.....

Date:.....

EACH MORNING: RECORD THE BEST OF TWO PEAK FLOW READINGS.
: "WHEEZE LAST NIGHT".
: "COUGH LAST NIGHT".

EACH EVENING: RECORD THE BEST OF TWO PEAK FLOW READINGS.
: NUMBER OF PUFFS SALBUTAMOL USED AND ANY OTHER MEDICATION USED.
: "ACTIVITY TODAY".
: "NASAL SYMPTOMS".
: "ABSCENCE" FROM WORK/CLASSES DUE TO ASTHMA.
: COMMENTS:
- UNUSUAL SIGNS AND SYMPTOMS.
- BEING AWAY FROM HOME
- EMOTIONAL UPSETS.
- FACTORS WHICH MAY HAVE AN EFFECT ON THE SEVERITY OF YOUR ASTHMA.

ASTHMA SEVERITY SCORE

SYMPTOM SCORE
0 NONE for 3 months
1 <once weekly or on excercise only
2 < daily but > once weekly
3 Daily, nights OK
4 Waking at night.

PUMP USE SCORE
0 Nil for 3 months
1 < once per week
2 < daily
3 1-4 times daily
4 > 4 times per day

Appendix C1

LAWRENCE TAK
TEL: 225-2041
225-2542
23-1806(H)

	SYMPTOM	PUMP USE	PEAK FLOW READING BEST	PEAK FLOW READING WORST	
Sunday 1					
Sunday 3					

PEAK FLOW METER

NAME:

AGE	HEIGHT	SEX	LLN
/rs	cm	♀ ♂	l/min

PHYSICIAN:

NEXT APPOINTMENT:

MEDICATION	DOSE	
SALBUTAMOL	100µg/PUFF	Number of doses actually taken during the last 24 hour period

WHEEZE LAST NIGHT	Good night	Woke 2-3 times due to wheeze
	Slept well, slightly wheezy	Bad night, awake most of time
COUGH LAST NIGHT	None	Moderately bad
	Little	Severe
WHEEZE TODAY	None	Moderately bad
	Little	Severe
ACTIVITY TODAY	Quite normal	Limited to slow walking
	Difficulty climbing stairs	Too breathless to walk
NASAL SYMPTOMS	None	Moderate
	Mild	Severe
NOTES:	ABSCENCE:	
	COMMENTS:	08.520 Iss. 2

DATE

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AM PM

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EACH MORNING:RECORD THE BEST OF TWO PEAK FLOW READINGS.
:"WHEEZE LAST NIGHT".
:"COUGH LAST NIGHT".

EACH EVENING:RECORD THE BEST OF TWO PEAK FLOW READINGS.
:NUMBER OF PUFFS SALBUTAMOL USED
AND ANY OTHER MEDICATION USED.
:"ACTIVITY TODAY".
:"NASAL SYMPTOMS".
:"ABSCENCE" FROM WORK/CLASSES DUE TO ASTHMA.
:COMMENTS:
-UNUSUAL SIGNS AND SYMPTOMS.
-BEING AWAY FROM HOME
-EMOTIONAL UPSETS.
-FACTORS WHICH MAY HAVE AN EFFECT
ON THE SEVERITY OF YOUR ASTHMA.

ASTHMA SEVERITY SCORE

Appendix C2

SYMPTOM SCORE
0 NONE for 3 months
1 <once weekly or on excercise only
2 < daily but > once weekly
3 Daily, nights OK
4 Waking at night.

PUMP USE SCORE
0 Nil for 3 months
1 < once per week
2 < daily
3 1-4 times daily
4 > 4 times per day

LAWRENCE TAK
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225-2542
23-1806(H)

	SYMPTOM	PUMP USE	PEAK FLOW READING BEST	PEAK FLOW READING WORST	
Sunday 7					

PEAK FLOW METER

NAME:

AGE		HEIGHT		SEX		LLN
yrs		cm		♀	♂	l/min

PHYSICIAN:

NEXT APPOINTMENT:

MEDICATION	DOSE
SALBUTAMOL	100µg/PUFF

Number of doses actually taken during the last 24 hour period

WHEEZE LAST NIGHT	Good night	Woke 2-3 times due to wheeze
	Slept well, slightly wheezy	Bad night, awake most of time
COUGH LAST NIGHT	None	Moderatery bad
	Little	Severe
WHEEZE TODAY	None	Moderatery bad
	Little	Severe
ACTIVITY TODAY	Quite normal	Limited to slow walking
	Difficulty climbing stairs	Too breathless to walk
NASAL SYMPTOMS	None	Moderate
	Mild	Severe

NOTES: ABSCENCE:

COMMENTS:

08.520 Iss. 2

DATE	SUN	MON	TUES	WED	THURS	FRI	SAT	SUN	MON	TUES	WED	THURS	FRI	SAT	SUN	MON	TUES	WED	THURS	FRI	SAT	SUN	MON	TUES	WED	THURS	FRI	SAT	SUN	MON	TUES
	X																													
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28			

EACH MORNING:RECORD THE BEST OF TWO PEAK FLOW READINGS.
:"WHEEZE LAST NIGHT".
:"COUGH LAST NIGHT".

EACH EVENING:RECORD THE BEST OF TWO PEAK FLOW READINGS.
:NUMBER OF PUFFS SALBUTAMOL USED
AND ANY OTHER MEDICATION USED.
:"ACTIVITY TODAY".
:"NASAL SYMPTOMS".
:"ABSCENCE" FROM WORK/CLASSES DUE TO ASTHMA.
:COMMENTS:
-UNUSUAL SIGNS AND SYMPTOMS.
-BEING AWAY FROM HOME
-EMOTIONAL UPSETS.
-FACTORS WHICH MAY HAVE AN EFFECT
ON THE SEVERITY OF YOUR ASTHMA.

ASTHMA SEVERITY SCORE

Appendix C3

SYMPTOM SCORE	PUMP USE SCORE
0 NONE for 3 months	0 Nil for 3 months
1 <once weekly or on excercise only	1 < once per week
2 < daily but > once weekly	2 < daily
3 Daily, nights OK	3 1-4 times daily
4 Waking at night.	4 > 4 times per day

LAWRENCE TAK
TEL:225-2041
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23-1806(H)

	SYMPTOM	PUMP USE	PEAK FLOW READING BEST	PEAK FLOW READING WORST	
Sunday 11					

PEAK FLOW METER

NAME:

AGE	HEIGHT	SEX	LLN
yrs	cm	♀ ♂	l/min

PHYSICIAN:

NEXT APPOINTMENT:

MEDICATION	DOSE	
SALBUTAMOL	100µg/PUFF	Number of doses actually taken during the last 24 hour period

WHEEZE LAST NIGHT	Good night	Woke 2-3 times due to wheeze
	Slept well, slightly wheezy	Bad night, awake most of time
COUGH LAST NIGHT	None	Moderatery bad
	Little	Severe
WHEEZE TODAY	None	Moderatery bad
	Little	Severe
ACTIVITY TODAY	Quite normal	Limited to slow walking
	Difficulty climbing stairs	Too breathless to walk
NASAL SYMPTOMS	None	Moderate
	Mild	Severe
NOTES:	ABSCENCE:	
	COMMENTS:	

08.520 Iss. 2

DATE

SUN MON TUES WED THURS FRI SAT SUN MON TUES WED THURS FRI SAT SUN MON TUES WED THURS FRI SAT SUN MON TUES WED THURS FRI SAT SUN MON TUES

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Appendix D

Asthma Quality of Life Questionnaire

(Marks et al., 1992)

Thank you for taking part in this questionnaire. It will help us to understand how asthma affects your life. Answers will be treated confidentially.
Mark the box which most closely describes how your asthma affected you over the last **four weeks.**

	Not at all	Mildly	Moderately	Severely	Very Severely
1. I have been troubled by episodes of shortness of breath.	0	1	2	3	4
2. I have been troubled by wheezing attacks.	0	1	2	3	4
3. I have been troubled by tightness of the chest.	0	1	2	3	4
4. I have been restricted in walking down the street on level ground or doing light house work.	0	1	2	3	4
5. I have been restricted in walking up hills or doing heavy house work.	0	1	2	3	4
6. I have felt tired or a general lack of energy.	0	1	2	3	4
8. I have been unable to sleep at night.	0	1	2	3	4
8. I have felt sad or depressed.	0	1	2	3	4
9. I have felt frustrated with myself.	0	1	2	3	4
10. I have felt anxious, under tension or stressed.	0	1	2	3	4

Asthma Quality of Life Questionnaire (Ctd.)

	Not at all	Mildly	Moderately	Severely	Very Severely
11. I have felt that asthma is preventing me from achieving what I want from life.	0	1	2	3	4
12. Asthma has interfered with my social life.	0	1	2	3	4
13. I have been limited in going to certain places because they are bad for my asthma.	0	1	2	3	4
14. I have been limited in going to certain places because I have been afraid of getting asthma and not getting help.	0	1	2	3	4
15. I have been restricted in sports, hobbies or other recreation I can engage in because of my asthma.	0	1	2	3	4
16. I have felt generally restricted.	0	1	2	3	4
17. I have felt that asthma is controlling my life.	0	1	2	3	4
18. I have been worried about my present and future health because of my asthma.	0	1	2	3	4
19. I have worried about asthma shortening my life.	0	1	2	3	4
20. I have felt dependant on my asthma sprays.	0	1	2	3	4

Name:..... Date:.....

Instructions for completing Record Sheet

A. Each morning on getting out of bed.

Do peak expiratory flow reading. Zero the indicator. Hold the peak flow meter horizontally. Blow out as forcefully as possible, with lips sealed around the mouthpiece. Record the best of three consecutive readings. It is not necessary to "zero" the instrument between readings. The highest reading will then automatically be recorded.

B. Each night at bedtime.

1. Record the number of times to activated your pump in the last 24 hours.
2. Record all other medicines taken during the last 24 hours.

C. *Asthma severity score.

Done on specified Sundays, in addition to normal readings. Fill in the number which corresponds to your SYMPTOM SCORE and PUMP USE SCORE.

Record the best of reading for the day, taken before the use of your asthma pump. Also, record the worst reading for the day. A few reading must be taken throughout the day.

D. Taking you homoeopathic medicines.

Do not touch the pills with your hands. Use the cap of the bottle to transfer them to your mouth. Allow the pillules to dissolve under the tongue. Do not eat, smoke, drink or brush your teeth for 15 minutes before and after taking the pillules. If this cannot be avoided: rinse your mouth with a little warm water before taking your pillules.

Store the medicines away from direct sun light and strong smelling substances such as camphor, hand creams and perfumes.

The different pills look the same, because the homoeopathic medication is impregnated onto the surface of the lactose pillules, and allowed to be absorbed.

Using your asthma pump (Salbutamol).

1. Shake the pump vigorously to ensure even mixing of the canister's contents.

2. Remove the mouthpiece cover.

3. Hold the inhaler so that the mouthpiece opening is pointed directly to the back of your throat.

4. Place the mouthpiece into your mouth and close your lips around it. Remember to open your mouth so that the mouthpiece can fit between the upper and lower teeth.

5. Press the canister down-wards to release one metered dose, a split second after starting to inhale deeply. Continue inhaling until your lungs are filled. Hold your breath for as long as is comfortably possible.

6. Breathe out slowly. If a second inhalation is required, wait for at least one minute before repeating the above process.

(Information supplied by Allen and Hanbury's in The South African Pharmaceutical Journal **58**(11) Nov 1991)

Appendix G

Frequency of remedies used in each group.

Remedy (15CH)	Placebo group	Treatment group	Remedy Total
Argentum nitricum	1	0	1
Arsenicum album	3	0	3
Calcarea carbonicum	2	6	8
Lycopodium clavatum	4	0	4
Natrum muriaticum	2	4	6
Natrum sulphuricum	2	1	3
Nux vomica	1	0	1
Phosphorus	0	0	0
Pulsatilla pratensis	1	5	6
Sepia officinalis	0	0	0
Silica terra	0	0	0
Sulphur	0	0	0
Total:	16	16	32