THE EFFICACY OF *SABADILLA OFFICINARUM 30CH AND 200CH* IN THE TREATMENT OF ALLERGIC RHINITIS

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Master of Technology: Homoeopathy

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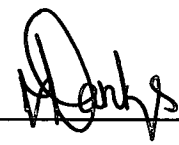
DECLARATION

I declare that this research report is my own, unaided work. It is being submitted for the Degree of Master of Technology: Homoeopathy at the Technikon Witwatersrand, Johannesburg. It has not previously been submitted for any degree or examination in any other Technikon or University.



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ABSTRACT

Allergic rhinitis, otherwise referred to as hay fever, is a common allergic reaction affecting the nose, throat, eyes, and respiratory system, of persons of all ages and both sexes. This study attempted to demonstrate the effect of the homoeopathically prepared remedy *Sabadilla officinarum 30CH and Sabadilla officinarum 200CH* in the treatment of allergic rhinitis.

Thirty participants were selected for this one hour, double-blind, placebo-controlled study. The participants were randomly placed into one of three groups of ten, consisting of the control group, and the two experimental groups. The control group received the placebo medication. The first experimental group received *Sabadilla officinarum 30CH*, and the second experimental group received *Sabadilla officinarum 200CH*. The patients were all supplied with: a stat dose of medication to use at the time of an allergic rhinitis attack, a diary card on which to score the severity of their symptoms at the time of such an attack, and a response to treatment questionnaire to fill in after the completion of their treatment.

The results were statistically analysed using the Wilcoxon Signed Ranks Test, the Kruskal Wallis Test, and descriptive statistics. The results show that treatment with *Sabadilla officinarum 30CH and 200CH* had a significant effect in improving the symptoms of allergic rhinitis.

I would like to dedicate this research to
my family, namely Mum and Nadine, and to Marelize,
for their love, support and encouragement throughout this process.

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TABLE OF CONTENTS PAGE

LIST OF FIGURES

LIST OF TABLES

LIST OF TABLES

CHAPTER ONE

INTRODUCTION

1.1 Statement of the Problem

Allergic rhinitis, otherwise referred to as hay fever, is a common allergic reaction affecting the nose, throat, eyes, and respiratory system, of persons of all age groups and both sexes (Geddes and Grosset, 2001). Conventional treatments result in many associated side effects that are not seen with the homoeopathic treatment of allergic rhinitis. This study aimed to prove that the homoeopathic remedy, *Sabadilla officinarum,* prepared at potencies of 30CH and 200CH respectively, can be successfully used to treat allergic rhinitis.

1.2 Importance of the Problem

A drastic rise in the occurrence of hypersensitivity reactions (allergies) has been witnessed in the last fifty years, especially in industrialized countries (Frase and Weiser, 1995). A recent study by Marshall *et al.* reveals a marked impairment in verbal learning, decision-making speed, and psychomotor speed in those who suffer from allergies, resulting in frequent absenteeism from work, or substantial decrease in productivity in the workplace (Thornhill and Kelly, 2000). It is estimated that between ten and twenty percent of the South African population suffers from an allergic disorder, and despite medical advances they remain a frequent and important cause of morbidity in many patients (Pharmacia Diagnostics and Medical Specialities, 1987).

Allergic rhinitis continues to flourish worldwide despite the advances and development of drugs and other treatments. A study conducted by Adventis Pharmaceuticals found that twenty-five percent of sufferers do not get relief from their symptoms, despite having taken conventional medication (Levy, 2000). The problem of hay fever is still a

great concern, as it is impossible to remove the cause thereof (allergens) from the environment. More and more patients are turning to complementary alternative medicines in order to find relief from their condition. In North America, allergic rhinitis is the leading reason for consulting a homoeopathic doctor (Poitevin, 1998).

1.3 Hypotheses

The first hypothesis stated that *Sabadilla officinarum 30CH and Sabadilla officinarum 200CH* would have a positive effect in the treatment of allergic rhinitis.

The null hypothesis stated that *Sabadilla officinarum 30CH and Sabadilla officinarum 200CH* would have no effect in the treatment of allergic rhinitis.

1.4 Aim of the Study

The aim of the study was to determine the efficacy of homoeopathically prepared *Sabadilla officinarum 30CH and Sabadilla officinarum 200CH* in the treatment of allergic rhinitis. This study aims to prove that *Sabadilla officinarum 30CH and Sabadilla officinarum 200CH* reduce the severity of allergic rhinitis, and may possibly offer an alternative form of treatment to conventional methods, without the adverse effects.

CHAPTER TWO

LITERATURE REVIEW

2.1 Allergic Rhinitis

2.1.1 Definition of Allergic Rhinitis

Allergy is a hypersensitive reaction to antigens (particular allergens or foreign substances), following initial sensitisation contact. These foreign substances are harmless to the great majority of individuals, however initial sensitisation occurs when a predisposed individual is exposed to an allergen. Allergens are any substance capable of inducing an allergic state, and include: pollen, animal dander, feathers, smoke, dust, fungi, bacteria, viruses, animal parasites, foods, and drugs. This hypersensitive reaction seen in hay fever, asthma, and urticaria is due to an antigen-antibody reaction. The antigen, usually a protein, stimulates the production of antibodies, and reacts specifically with those antibodies. Antibodies are specific protein substances in the blood that destroy, or render inactive certain foreign substances, usually proteins, and may be developed naturally or in response to a specific antigen that has been introduced into the body parentally or otherwise (Blackwell, 1997).

Allergic rhinitis is inflammation of the nasal mucous membrane as a result of any effective allergen such as pollen, and is commonly referred to as hay fever (Mygind *et al.*, 1997). However, this is not an accurate term, in that the pollen of hay grasses is only one of the many allergens responsible for this condition, and there is absence of a fever (Rapp and Frankland, 1976, Vogt, 1990 and Paradox, 2001). Accurate differentiation between allergic rhinitis and hay fever is imperfect in clinical practise, as no standardized definition has been provided for the purposes of epidemiology (Kay, 1997). For the purposes of this study, the terms allergic rhinitis and hay fever are used interchangeably, and are considered to be one and the same thing. Allergic rhinitis is best defined as an inflammation of the nasal mucous membranes (Clement, 1997), and is

characterized by paroxysms of sneezing, nasal congestion, rhinorrhoea, nasopharyngeal pruritis, and associated eye symptoms, although patients may not have the entire symptom complex (Ricketti, 1997), and may only present with two or more symptoms occurring for more than an hour on the days of an allergic attack (Mackay and Durham, 1997).

2.1.2 Incidence of Allergic Rhinitis

Allergic rhinitis affects a very large percentage of the population worldwide. One in five of the British population, approximately thirty five million Americans, and an estimated twenty five percent of South Africans suffer from this condition (Steven, 1999). It accounts for frequent absenteeism from work and visits to a physician for medical treatment amounting to costs well over one billion dollars in North America in 1987 (Weldon, 1998). Alone, allergy treatment costs the American healthcare system eighteen billion dollars annually (NIAID, 2002).

Predisposing factors are a positive family history of similar symptoms, and a personal history of co-existing allergies manifesting as asthma, eczematous dermatitis, and urticaria (Thornhill and Kelly, 2000). In fact, allergic rhinitis may be the sole manifestation of allergy, or present in individuals with a history of the aforementioned allergic problems (Vogt, 1990). But, by far the single, most important factor predisposing a child to the development of both allergic rhinitis and asthma is the presence of other cases in the household. The exact role of genetic predisposition remains unclear, but it would appear that common genetic factors permit, rather than cause the susceptibility to, and development of allergy (Middleton *et al.*, 1983).

Although allergic rhinitis may have its onset at any age, the incidence of onset is greatest in adolescence between the ages of twelve and fifteen years (Weldon, 1998). Typically, the symptoms remain constant for twenty to thirty years, improve considerably during middle age, and are almost completely resolved in old age (Mygind *et al.*, 1997).

Boys tend to have an increased incidence of allergic rhinitis in childhood, but the sex ratio evens out by the time of adolescence (Ricketti, 1997). Allergic rhinitis is more common in upper than lower social classes, and in negros than caucasians (Sibbald, 1993).

2.1.3 Classification of Allergic Rhinitis

Allergic rhinitis can be categorized as seasonal rhinitis, and non-seasonal or perennial rhinitis (Clement, 1997). With seasonal rhinitis, the exacerbations of symptoms occur at specific times during the year, whereas patients who suffer from perennial rhinitis have symptoms all year-round, without seasonal variation. However, seasonal exacerbations of perennial rhinitis can occur (Norris, 1995), and the symptoms of allergic rhinitis may exhibit periodicity within a season. In both cases the patient is capable of dating the onset of symptoms to a specific week or month (Ricketti, 1997).

There is little difference between the presenting symptoms of seasonal allergic rhinitis and perennial allergic rhinitis, making the differential diagnosis difficult. This is further compounded, as there is no universally accepted diagnostic test for rhinitis that is applicable for epidemiological studies. Much of the understanding of this condition is derived from self- or physician diagnosis based on symptom experience and reporting, which is largely subjective. The data for seasonal allergic rhinitis, in which the timing and repeated occurrence of symptoms is characteristic, is thus more secure than for perennial allergic rhinitis, for which there are many confounding factors (Howarth, 1997).

The timing of symptoms clues the physician to the likely sensitising allergens and classification of allergic rhinitis. Seasonal allergic rhinitis is caused mainly by grass and tree pollens, and occurs mainly in springtime and in late summer and autumn (Vogt, 1990). Perennial allergic rhinitis is more difficult to diagnose, especially if the patient presents with symptoms of sinusitis or a 'permanent cold'. The most common allergen

accounting for perennial allergic rhinitis symptoms is the house dust mite (Mackay and Durham, 1997).

2.1.4 Aetiology of Allergic Rhinitis

In the typical patient presenting with allergic rhinitis, signs and symptoms are ascribed to an immediate hypersensitivity reaction to various allergens (antigens). The allergen responsible for allergic rhinitis is almost always an inhalant (aero-allergen), most commonly pollens, house dust mites, mould spores, animal dander, and occupational allergens (Lieberman and Crawford, 1982).

Seasonal allergic rhinitis corresponds to the reaction to an allergen such as pollen (Clemant, 1997). The pollens responsible for causing seasonal allergic rhinitis originate from plants that depend on wind, and not insect, pollination. These include many grasses, trees, and weeds which produce lightweight pollen in sufficient quantities to sensitise individuals with genetic susceptibility. Other known allergens are airborne moulds (Ricketti, 1997).

Perennial allergic rhinitis corresponds to other allergens of which inhalant allergens are the most important cause. These include: animal dander, cockroaches, house dust mites, feather pillows, and mould antigens. Pollen allergy and exposure to occupational allergens may contribute to seasonal exacerbations of perennial allergic rhinitis. In these cases symptoms are perennial but not constant, because there is a clear temporal association with allergen exposure. Other causative factors of perennial allergic rhinitis are non-specific irritants such as tobacco smoke, perfume, paint, newspaper ink, soap powders and chemical fumes. Non-specific air pollutants such as carbon monoxide, nitrogen dioxide, ozone and sulphur dioxide may also potentiate the symptoms of allergic rhinitis (Kay, 1997 and Vogt, 1990). The symptoms of allergic rhinitis, are further aggravated by draughts and sudden changes in weather (Thornhill and Kelly, 2000).

2.1.5 Anatomy and Physiology of the Nose

The nose is the primary passageway for air entering the respiratory system (Martini, 1995). As inhaled air passes through the nose, three distinct functions are performed by the nasal cavities, namely: warming the air, humidifying the air, and filtering the air (Guyton and Hall, 1996).

The paired nasal cavities are passages that start at the nostrils (anterior nares) and remain separate until they unite in the posterior nares which open into the nasopharynx (Howarth, 1997). The nasal cavities are separated by the nasal septum which forms the medial wall of the nasal cavity. The lateral wall of the nasal cavity is formed by the turbinates (nasal conchae) (Martini, 1995).

The inside of the nose is lined with a mucous membrane which contains coarse hairs that trap large airborne particles such as sand and insects, preventing them from entering the nasal cavity, and is important for its function of filtration of inhaled air. The efficacy of the nasal filter is dependant on the size of the inhaled particles. The mucous membrane also retains ninety-nine percent of inhaled water-soluble gases such as sulphur dioxide, ozone, and formaldehyde, which are known irritants of the nasal mucosa (Mygind *et al.*, 1997).

The sensory innervation of the nose is predominately supplied by the olfactory and trigeminal nerves. The ophthalmic and maxillary branches of the trigeminal nerve are responsible for the irritation of sneezing and nasal hypersecretion. The primary neurotransmitter is noradrenaline which has vasoconstrictor activity. The nasal vasculature is under sympathetic control, with stimulation inducing vasoconstriction and a reduction in blood flow to the nasal mucosa. Thus an increase in sympathetic tone decreases nasal congestion by reducing blood flow (Howarth, 1997).

Due to its effective filtering action for allergens in the inhaled air, the nose is the site of more allergic symptoms and illnesses than any other organ (Mygind *et al.*, 1997).

2.1.6 Pathogenisis of Allergic Rhinitis

Although the understanding of the pathogenesis of allergic rhinitis has increased substantially in the last few years, our knowledge of the sensitisation process is still incomplete. Evidence indicates that associations may exist between allergy development and other factors such as viral infections in the airways. At this time, the importance of these factors has not yet been established (Mygind *et al.*, 1997)

Allergic rhinitis is the prototype of hereditary allergic (atopic) respiratory disease, and is an immunoglobulin E (IgE) mediated Type I hypersensitivity response produced by the union of an environmental antigen (allergen) and the antibody IgE (Norris, 1995). Inhalation of the allergen brings it into contact with the upper airway and, possibly, the lower airway mucosa. The allergen, which is typically a protein, is recognized by IgE molecules with relatively high specificity that bind to high-affinity receptors on mast cells, basophils, and eosinophils. This recognition leads to the activation of the mast cell and basophils, and the subsequent release of inflammatory mediator substances, usually in the form of histamine, eliciting an allergen-antibody reaction in the nose that produces the allergic symptoms (Togias, 2000 and Ricketti, 1997).

2.1.6.1 Mast Cells

Mast cells are large, round, plump, granulated cells containing heparin, histamine, bradykinin, and serotonin (Blackwell, 1997), and have an outer coating of IgE antibodies. Mast cells are constitutive cells of the normal nasal mucosa, but are not usually found superficially within the airway epithelium except in the conditions of both seasonal and perennial allergic rhinitis. Mast cells are the pivotal cells in terms of allergic reaction, as they promote the development of subacute and, eventually chronic nasal inflammation (Togias, 2000 and Howarth, 1997). Mast cell degranulation, alone, accounts for approximately one half of the symptoms of allergic rhinitis (Thornhill and Kelly, 2000).

In allergic rhinitis, the epithelial mast cells are in an activated state, with both ultrastructural changes of degranulation evident on microscopy, and elevated levels of the mast cell mediators histamine and tryptase evident in nasal lavage fluid (Howarth, 1997).

2.1.6.2 Lymphocytes

Other cells that contribute to the allergic reaction are lymphocytes. Lymphocytes are a variety of white blood cells that are formed in the lymphoid tissue of the body, and are round and colourless. Lymphocytes make up twenty to thirty percent of the total white blood cells, and serve as a defense mechanism for the body, as their function is to produce antibodies. Lymphocytes can be directly activated by allergens through antigen-presenting cells. This results in the additional release of cytokines, which have the same effects on the vasculature that occur when mast cells are activated. When a person with allergic rhinitis is exposed to an allergen, tremendous cellularity develops in the submucosa within twenty-four hours. These cells are predominantly thymus lymphocytes (T- lymphocytes, which are pre-processed in the thymus), but eosinophils congregate as well, creating a lymphocytic and eosinophilic infiltrate (Blackwell, 1997 and Togias, 2000).

2.1.6.3 Eosinophils

In addition to the effects of acute mast cell degranulation on immediate acute symptoms, mast cell degranulation will contribute to the eosinophilic mucosal inflammation which is evident in allergic rhinitis. Eosinophils are a type of white blood cell that increase in number during allergic states, and release major basic protein which further disrupts the respiratory epithelium, and, in turn promotes increased mast cell mediator release. Other evidence for the participation of eosinophils in allergic inflammation is their measurable increase during seasonal exposure (Ricketti, 1997). However, the absence of total eosinophilia (the increase above normal in the number of eosinophils per unit volume in peripheral blood) does not rule out the diagnosis of allergic rhinitis (Vogt, 1990).

2.1.6.4 Basophils

With continuation of allergic inflammation there is an accumulation of basophils (Ricketti, 1997). Basophils are white blood cells that possess fewer, larger granules and differ from the mast cell in that they contain less histamine. However, they too possess high-affinity IgE receptors. Basophils are now also appreciated to be capable of synthesizing certain cytokinins (Howarth, 1997).

2.1.6.5 Inflammatory Mediators

Various preformed mediators such as histamine, trypase, cytokines, and heparin are released by the mast cell. Histamine is the principal inflammatory mediator in allergic rhinitis. Histamine stimulates histamine one (H_1) receptors on the sensory nerves of almost every end organ in the nasal tissue, and produces every symptom of the constellation that constitutes allergic rhinitis. Histamine also stimulates histamine two (H_2) receptors located at vascular sites, and leads to plasma extravasation and congestion. The nasal effects of histamine are primarily H_1-receptor mediated with respects to itch, sneeze and nasal discharge. H_2-receptor blockade exerts an effect on rhinorrhoea and nasal blockage (Howarth, 1997).

Preformed tryptase is also found in the mast cells, and while its exact role is not yet fully understood, it is known to break down kininogen in the blood, which leads to the generation of kinins which are extremely potent inflammatory substances. The cytokines released by the mast cells have a potent effect on the endothelium, which leads to the expression of adhesion molecules and the attraction of additional inflammatory cells (Howarth, 1997 and Togias, 2000).

Lipid mediators such as the sulphidopeptide leukotrienes, and prostaglandin are also released by the mast cells during an allergic reaction. Leukotrienes too have strong effects on blood vessels, but a lesser effect on the submucosal glands, and no stimulatory effect on sensory nerves. In fact, leukotrienes appear to be of relatively greater

importance than histamine in the genesis of nasal blockage (Howarth, 1997). The role of prostaglandin is not yet defined (Togias, 2000 and Howart, 1997).

2.1.6.6 Sensory Reflexes and Responses

The activation of the sensory nerves during the allergic reaction is the most important element in the generation of the acute symptoms of allergic rhinitis, causing the stimulation of reflexes that affect the end organ, namely the nose, via the efferent pathway. Reflexes stimulate the submucosal glands, and are responsible for the sneezing, itching, and hypersecretion typical of allergic rhinitis. The nasal vasculature is pivotal in the generation of nasal obstruction, and is characterized by the presence of capacitance vessels, under control of neural and humoral agents, that are capable of expanding quickly. (Togias, 2000 and Mygind *et al.*, 1997). Nasal hyperreactivity may occur due to: hyperreactive sensorineral apparatus, hyperaesthesia of the central nervous system, inflammation of the nerves in the efferent pathway, or as a result of the end organs, vasculature or glands being altered by the allergic inflammation themselves, and becoming hypersensitive to natural stimuli. This creates a setting for irritants, not just allergens, to activate the sensory nerves and increase the inflammatory picture and the symptoms of allergic rhinitis (Togias, 2000), as allergic rhinitis is characterized by increased reflex activity and a hyperreactive mucous membrane (Mygind *et al.*, 1997).

The acute reaction to allergen exposure in allergic rhinitis causes sneezing, nasal pruritis, rhinorrhoea, nasal congestion (Togias, 2000), pruritis of the soft palate referred into the ear along the eustachian tube, mucous production, and post-nasal drip (Weldon, 1998).

2.1.7 Clinical Features of Allergic Rhinitis

In allergic rhinitis, the major symptoms are: paroxysms of sneezing, profuse rhinorrhoea, inflammation of the nasal mucosa, nasal obstruction or congestion, pruritis of the nose, palate and ears, and ocular symptoms (Thornhill and Kelly, 2000). The

severity of signs and symptoms are periodic and show variation from year to year (Norris, 1995).

2.1.7.1 Sneezing

Sneezing is the most characteristic symptom of allergic rhinitis, and is prevalent in the morning (Vogt, 1990). Patients may have paroxysms of ten to twenty sneezes in rapid succession. Sneezing episodes may arise without warning, or may be preceded by irritation or uncomfortable itching in the nose. These sneezing attacks result in tearing of the eyes due to the activation of the lacrimal reflex in the lachyrimal apparatus (Ricketti, 1997).

2.1.7.2 Rhinorrhoea

The rhinorrhoea witnessed in allergic rhinitis is typically a profuse and continuous thin, watery discharge (Norris, 1995). This watery rhinorrhoea causes patients to sniffle, snort, and blow their noses often. Due to the copious nature of the rhinorrhoea, the skin of the external nose and upper lip may become irritated, red and tender. A purulent discharge is not usually seen in uncomplicated allergic rhinitis in the absence of a secondary infection, however the discharge can appear yellowish due to clustering of eosinophils (Vogt, 1990).

2.1.7.3 Inflammation of the Nasal Mucosa

With allergic rhinitis, the nasal mucosa is usually pale, and cyanotic and presents with a bluish discolouration of the nasal conchae (Vogt, 1990). The nasal passages may appear pale and boggy, or sometimes reddened or excoriated (Thornhill and Kelly, 2000). Since the nasal mucosa is continuous with that of the paranasal sinuses, congestion of the ostia between them may result in sinusitis and the secondary symptoms of anosmia (loss of smell), headache, facial pain or muco-purulent post-nasal drip (Mackay and Durham, 1997).

2.1.7.4 Nasal Congestion and Nasal Obstruction

A frequent complaint of allergic rhinitis is nasal congestion resulting from swollen nasal conchae. The congestion may be bilateral, or alternate when upright, and obstructed with recumbency (Vogt, 1990). There is stuffiness of the nose which may or may not be associated with the watery mucous, but may rather be due to sinusitis as a result of nasal allergies. In fact, chronic sinusitis often coexists with allergic rhinitis (Zoorob and Morelli, 2002). In children in particular, mouth breathing, secondary to the nasal congestion, is frequently witnessed. The voice may take on a nasal quality, and snoring and sore throats from nasopharyngeal dryness due to mouth breathing are other symptoms related to nasal congestion. Other complications of mouth breathing include: characteristic facial features, halitosis, gingival hypertrophy, and enlargement of pharyngeal lymphoid tissue (Vogt, 1990).

The nasal obstruction experienced in allergic rhinitis may be episodic and intermittent, more troublesome in the evenings, or continuous (Vogt, 1990). If the nasal obstruction is severe, interference with the aeration of the paranasal sinuses or the eustachian tube may occur. Chronic nasal obstruction extending to eustacian tube obstruction is common, and may occasionally be the major or sole complaint, particularly in children (Norris, 1995).

2.1.7.5 Ocular symptoms

The ocular symptoms of allergic rhinitis are typically pruritis and lachrymation, often accompanying the nasal symptoms. Conjunctival and scleral swelling often occur (Ricketti, 1997). The eyelids and conjunctivae are red, congested, and oedematous, and extranasal infections such as conjunctivitis may occur, with excessive lachrymation. Itching of the eyes results in rubbing that may aggravate the redness of the conjunctiva, puffiness of the eyelids, and cause tearing. Patients with severe eye symptoms often complain of photophobia and "tired", sore eyes. Another common manifestation of allergic rhinitis is "allergic shiners", dark bluish, circular shaped discolourations in the

infraorbital areas under the patient's eyes, caused by venous congestion in the maxillary sinuses (Norris, 1995).

2.1.7.6 Nasopharyngeal and Ear Symptoms

With allergic rhinitis, swelling of the nasal conchae is a common manifestation (Thornhill and Kelly, 2000). There may be marked itching of the nose, mouth, throat, ears and face which is extremely annoying. Itching in the nose is prominent, especially in children, inducing frequent rubbing of the nose. Hay fever patients typically wiggle or wrinkle their noses, and pick at their noses. The characteristic 'allergic salute', is accomplished by pushing or rubbing the nose in an upward (not sideways) manner towards the forehead, using the palm of the hand (Meltzer *et al.*, 1988). This results in a transverse nasal crease forming across the bridge of their nose, which is very characteristic of allergies (Vogt, 1990 and Rapp and Frankland, 1976).

Itching of the oropharynx is typical of allergic rhinitis, leading to tongue thrusting, rubbing, and gargling among other activities (Meltzer *et al.*, 1988). Clinical presentation of allergic rhinitis may also present with an injected pharynx (Thornhill and Kelly, 2000), and posterior pharyngeal drainage manifesting as a post-nasal drip, which gives rise to a hacking, non-productive cough and frequent throat-clearing (Vogt, 1990 and Ricketti, 1997).

Another common finding of allergic rhinitis is inflammation and swelling of the membranes of the ear (Thornhill and Kelly, 2000). There may be complaints of itchy ears and earache as a result of poor drainage of the eustachian tubes due to severe nasal obstruction, decreased hearing with sounds that seem muffled, or a crackling sensation in the ears worse on swallowing (Ricketti, 1997).

2.1.7.7 Mental symptoms

Mental symptoms of allergic rhinitis include malaise (Norris, 1995), irritability, listlessness, moodiness, sleepiness during the day, and trouble sleeping at night (Rapp and Frankland, 1976 and Ricketti, 1997).

2.1.7.8 Other Symptoms

Headache may occur in allergic rhinitis sufferers as a result of poor drainage of the eustachian tubes due to severe nasal obstruction. This headache is characteristic of the so-called vacuum type, presumably caused by the development of negative pressure when air is absorbed from the obstructive sinus (Ricketti, 1997).

Allergic rhinitis patients may experience a constrictive feeling in the chest, accompanying a cough, which may result in shortness of breath, and the sensation of tightness in the chest (Ricketti, 1997). This often results in breathing with an open mouth (Rapp and Frankland, 1976 and Vogt, 1990). These symptoms are more predominant at night, and the diagnosis of co-existing asthma should be considered in these patients (Ricketti, 1997).

Some patients experience systematic symptoms of allergic rhinitis, and complain of weakness, fatigue, anorexia, and abdominal discomfort (Ricketti, 1997). With continuous severe nasal congestion as a result of allergic rhinitis, the senses of taste and smell may be lost (Rapp and Frankland, 1976).

2.1.8 Diagnosis of Allergic Rhinitis

The diagnosis of allergic rhinitis is usually made on the clinical features, however it is important to exclude more sinister causes which may mimic allergic rhinitis:

- The first step is to exclude other diseases and structural abnormalities.

- Secondly, distinguish between non-infectious (non-purulent) and infectious (purulent) diseases.
- Thirdly, distinguish between allergic and non-allergic patient.

Exclude mechanical factors such as septal deviation, nasal polyps, paranasal tumours, and foreign bodies. Distinguish the symptoms from those commonly found in infections, such as the common cold, bacterial infection, immunodeficiency, and sinusitis. Other miscellaneous conditions that require differential diagnosis are rhinitis medicamentosa, anti-hypertensive drugs, pregnancy, and cocaine abuse (Mygind *et al.*, 1997). A firm diagnosis of allergic rhinitis relies on family history, the patient's personal history, and on objective physical findings during the symptomatic phase (Norris, 1995).

2.1.8.1 Blood Tests

Physical findings vary, depending on the severity of the allergic reaction (Weldon, 1998). Although it is appropriate to obtain a white blood cell differential count on a patient with suspected allergic rhinitis to examine for the possibility of eosinophilia, a raised eosinophil count of more than four hundred cells per millimetre-cubed. However, the absence of absolute eosinophilia does not rule out the possible diagnosis (Vogt, 1990).

In addition to a routine full blood count and eosinophil count, it is helpful to check immunoglobulin levels (Kay, 1997). Total IgE levels are particularly useful for screening for possible allergic disease in:

- Children under the age of three years.
- Patients sensitive to allergens other than aero-allergens.
- Patients who appear to be allergic despite negative specific allergy tests.

However, it must be noted that normal values for Total IgE levels vary with age, and that the Total IgE may well be within normal limits despite severe allergy in a small organ such as the nose (Norris, 1995 and Potter and Buys, 2001).

2.1.8.2 Histiological Tests

Microscopic examination of nasal-lavage fluid and sputum are far more helpful laboratory tests, and reveal a large acummulation of eosinophils in patients with allergic rhinitis. It is thus not suprising that nasal eosinophilia is regarded as a hallmark of nasal allergy. Eosinophils are best seen on a nasal smear using Hansels stain. The percentage of eosinophils seen on nasal smear ranges from: ten to one hundred per cent. As eosinophil numbers reduce as the patient improves, a grading scale may be used to monitor the response to treatment (Mackay and Durham, 1997 and Potter and Buys, 2001).

2.1.8.3 Skin Prick Tests

Skin prick tests are cheap, simple and quick, and can be performed by any practitioner trained in the technique. The test is dependant on the the introduction of an allergen extract into the dermis, best performed on the inner aspect of the forearm, resulting in an IgE-mediated response which is characterized by an immediate wheal and flare reaction (Toerin *et al.*, 2001). In some instances these tests yield valuable clues when considered with the examination and patient history (Mackay and Durham, 1997). Skin tests are generally reliable for the identification of aero-allergens. Only high-quality, biologically standardized allergen-extracts should be used. The standardized skin prick test available in South Africa has nine to ten aero-allergens, including: house dust mite, cockroach, cat saliva, dog epithelium, bermuda grass, maize pollen, a grass mix, a tree mix, and moulds. These tests should never be performed on patients suffering from severe eczema, and are also contraindicated in patients who are currently taking antihistamines, as they effectively block the wheal and flare reaction. Skin testing for inoculant allergens such as horse antigens and bee venom should only be performed by specialists in a hospital environment (Potter and Buys, 2001).

2.1.8.4 Radio-Allergo-Sorbent Technique (RAST Tests)

When skin-prick tests are not possible, blood allergen specific IgE concentrates may be determined by doing RAST tests. However these tests are very expensive and offer little additional information (Mackay and Durham, 1997).

2.1.9 Complications of Allergic Rhinitis

Despite the prevalence of allergic rhinitis, this condition is often treated inadequately and becomes chronic, leading to a chronic state of nasal inflammation resulting in the development of an obstruction. This frequently results in more serious complications in the upper and lower airways (Skoner, 2000). Left untreated, patients with rhinitis can develop other serious medical problems such as upper-respiratory tract infections which contribute to increased airway hyper-reactivity in patients with allergic rhinitis and asthma (Weldon, 1998).

Epidemiologic surveys have shown that allergic rhinitis is closely associated, and may be a causative factor of asthma, sinusitis, and otitis media with effusion. These studies demonstrate that up to seventy-eight percent of patients with asthma are diagnosed with allergic rhinitis (Pederson and Migind, 1982), and ninety-nine percent of adults and ninety-three percent of adolescents with allergic asthma also have allergic rhinitis. Conversely, asthma is diagnosed in up to thirty-seven percent of patients who suffer from seasonal rhinitis. Numerous studies have also documented the prevalence of allergic rhinitis in patients with both acute and chronic sinusitis, documenting the co-existance of allergic rhinitis and sinusitis. Obstruction and dysfunction of the eustacian tube because of inflammation caused by seasonal or perennial allergic rhinitis can lead to chronic otitis media with effusion (Skoner, 2000).

Other common complications of allergic rhinitis include: nose bleeds, ear, throat and chest infections and nasal polyps (Martini, 1995).

2.1.10 Quality of Life and Psychological Impact of Allergic Rhinitis

While allegic rhinitis is not necessary life-threatening, it severely impacts on quality of life. As a rule, patients with allergic rhinitis feel that their quality of life is worse compared to the general population. They feel they have more fatigue, physical limitations, impaired concentration, decreased or limited social functioning, and an overall poorer self-image compared with non-allergic patients (Mackay and Durham, 1997 and Weldon, 1998). A recent study by Marshall *et al.* reveals significant impairment of psychomotor speed, verbal learning, and decision-making speed in patients afflicted with allergies (Thornhill and Kelly, 2000). Young people with allergic rhinitis especially have a general feeling of malaise and feel limited in their ability to perform daily tasks resulting in poor self-esteem (Fineman, 2002). So commonplace are these mental symptoms, which are out of proportion to objective evidence despite optimal medications and environmental controls, that is accepted practice to wait six months before considering a diagnosis of undifferentiated somatoform disorder (Weldon, 1998).

2.2 Conventional Treatment:

2.2.1 Overview

Patients with severe symptoms of allergic rhinitis will almost always require medication to relieve their condition. Whereas environmental control measures may reduce the intensity of perennial allergic rhinitis because of indoor allergens, in the majority of cases supplemental medical therapy will also be needed. Several different classes of medication are available for the treatment of allergic rhinitis (Corren, 2000). Treatments must be individualized, as not all regimes will work for each patient. The conventional treatment of allergic rhinitis tends to be multi-faceted (Clement, 1997). In prescribing medications for allergic rhinitis, the physician should always consider costs, limitations, indications, and adverse effects (Weldon, 1998). Anti-histamines, steroid nasal sprays, and immunotherapy are commonly used (Mygind *et al.*, 1997). However, beyond the impairments caused by the systemic effects of the disease itself, there is also considerable impairment associated with the adverse effects of over the counter (OTC) medications used to treat allergic rhinitis (Fineman, 2002).

2.2.2 Drug Pharmacopoeia

2.2.2.1 Antihistamines

Antihistamines comprise the largest group of allergic rhinitis drugs on the market (Thornhill and Kelly, 2000). H1 antihistamines are the most commonly prescribed, and are the foundation of symptomatic treatment of allergic rhinitis as they are the most useful in controlling the sneezing, pruritis and rhinorrhoea that occur in allergic rhinitis. However, they are less effective against the ocular symptoms and nasal obstruction in these patients (Myding *et al.*, 1997).

Antihistamines are compounds of various chemical structures that have the ability to antagonize some of the actions of histamine by competitively blocking the effect of

histamine on the nasal and ocular mucosa (Weldon, 1998). In clinical use these drugs are most effective when given early, at the first appearance of symptoms, because they do not abolish the existing effects of histamine, but rather prevent the development of new symptoms caused by further histamine release (Ricketti, 1997).

All the antihistamines are readily absorbed after oral administration, but vary in speed, intensity, and duration of effect (Ricketti, 1997). Because most antihistamines have a relatively rapid onset of action (one to three hours), they are frequently used on an intermittent, as-required basis (Corren, 2000).

First-generation antihistamines, namely clestamine and chlorpheniramine, effectively block histamine effects, but commonly produce anticholinergic adverse effects such as: sedation, fatigue, nervousness, dizziness, impairment of cognitive function, blurred vision, dry mouth, nausea (Norris, 1995), vertigo, gastrointestinal upset, irritability in children, and general depressed effect on the central nervous system (CNS) (Ricketti, 1997). This is because these drugs readily cross the blood-brain barrier and bind not only to H1-histamine receptors, but also to dopaminergic, serotinergic, and cholinergic receptors. This furthermore explains why serious work accidents are more closely associated with first-generation antihistamines than any other class of medication (Gilmore *et al.*, 1996). Therefore first-generation antihistamines must be prescribed with caution in most patients, but should be absolutely avoided in patients who have pre-existing intellectual impairment, operate heavy machinery, drive extensively, and who pilot planes (Corren, 2000). Drug interactions are also suspected with some anti-depressant drugs, and human immunodeficiency virus (HIV) -specific protease inhibitors (Milgrom and Bender, 1997).

Newer, second-generation antihistamines have been shown to be at least as clinically effective as first-generation antihistamines, but because they are larger and more lipophobic they do not readily cross the blood-brain barrier. They also display greater affinity to the H1-histamine receptors and have little affinity for the other receptors (Corren, 2000). Second-generation antihistamines also have the advantages of rapid

onset of action as well as less frequent dosing (Shearer, 1998). Drugs such as astemizole, terfenadine, loratadine and cetrizine produce fewer sedating effects, do not affect performance, and have no anticholinergic effects. However when combined with other drugs such as macrolide antibiotics, or in the case of overdose, the use of terfenadine and astemizole may result in cardiac arrythmia and occasionally in sudden cardiac death. As a result, neither of these agents is available in the United States (Corren, 2000 and Weldon, 1998).

Even newer, third-generation antihistamines such as fexofenadine hydrochloride (Telfast) (Potter and Schoeman, 2001) have been developed and approved for use. Whereas, deslortadine and norastemizole are still being subjected to clinical trials (Corren, 2002).

Because of the wide range of antihistamines available, the physician should become familiar with selected antihistamines for use. This choice should be based on the effectiveness of antihistamine activity, and the limitation of side effects (Ricketti, 1997).

Although alternative forms of therapy are available, and preferable in many cases, patients with allergic rhinitis who do have medical-aid often resort to self-medication with OTC first-generation antihistamines (Corren, 2000).

2.2.2.2 Corticosteroids

Topical intranasal corticosteroids are currently the most potent medication available for the treatment of allergic rhinitis (Mygind *et al.*, 1997). Intranasal steroids have been proven useful in relieving the symptoms of sneezing, rhinorrhoea and congestion, and may be equally useful in relieving pharyngeal pruritis and cough related to allergic rhinitis. This class of agents works best when taken regularly on a daily basis because of their rapid onset of action (within twelve to twenty-four hours) (Corren, 2000). However, it may also be moderately effective when used intermittently (Juniper *et al.*, 1993).

Cortisone and its derivatives have a significant beneficial effect in managing various allergic processes, although the mechanism of their therapeutic effect is not fully understood. The number of eosinophils and mast cells are reduced by topical steroids during seasonal exposure to allergens. Both beclomethasone flunislide and diproprionate have been used for several years for allergic rhinitis' treatment, and do not exhibit side effects such as suppression of adrenal function witnessed in older generation drugs such as dexamethasone. Even newer topical cortisones such as triamcinolone, fluticasone and budesonide have been released for clinical use (Ricketti, 1997).

A number of gluco-corticoid compounds are now available for intranasal use in allergic rhinitis in the form of both aerosols and aqueous formulations, and include: beclomethasone, budesonide, flunisolide, fluticasone proprionate, monetasone furoate, and triamcinolone.

The notable side effects of intranasal steroids include local dryness and irritation of the nasal mucosa, epistaxis, stinging, and sneezing, and with prolonged administration are a risk factor for septal perforation. Because there have been reported cases of nasal septal perforation, patients who use these medications for the chronic treatment of allergic rhinitis should be seen at yearly intervals (Corren, 2000).

Inhaled intranasal steroidal sprays produce local anti-inflammatory effects, but these drugs are not effective in acute exacerbations (Norris, 1995).

Systemic corticosteroids are generally regarded as being inappropriate therapy for patients with mild to moderate allergic rhinitis symptoms. However, some patients respond only to corticosteroids. In cases with marked nasal obstruction, topical steroids cannot be adequately distributed to the nose, and a systemic corticosteroid may be required for three to five days, and thereafter improvement can be maintained by the use of a topical corticosteroid spray. These oral and injectable steroids may offer rapid relief, however the frequency thereof should be limited only to patients who are refractory to other medications as they are a risk factor for cataracts and aseptic necrosis of the hips

(Weldon, 1998). As in the use of topical steroids, systemic steroids should only be reserved for severe cases that cannot be controlled by routine measures, and then only for a limited period and never on a chronic basis (Ricketti, 1997 and Weldon, 1998).

2.2.2.3 Cromolyn

Cromolyn sodium is employed to treat allergic and non-allergic rhinitis, and is now available OTC (Weldon, 1998). Topical intranasal cromolyn sodium has an extensive record of use in allergic rhinitis. It controls the symptoms of sneezing, itching, and rhinorrhoea as effectively as antihistamines when prescribed four times daily (Corren, 2000). It is poorly absorbed by the oral route, and is more effective when it is administered topically via inhalation or a direct spray into the nose. It has been shown to be effective as a prophylactic in the management of allergic rhinitis, by reducing sneezing, nasal pruritis and rhinorrhoea (Ricketti, 1997), but is not considered effective for acute symptomatology (Vogt, 1990).

The proposed mechanism of cromolyn sodium in allergic rhinitis is to stabilize the mast cells, and thereby prevent the antigen-induced degranulation and release of their inflammatory mediators. However, cromolyn sodium appears to be effective only against connective tissue-type mast cells, and has been shown to be less effective than the intranasal corticosteroids.

Nedocromil sodium is a newer derivative which appears to be effective against both mucosal and connective tissue-type mast cells. Like cromolyn, nedocromil is primarily recommended for prophylactic use (Ricketti, 1997).

Adverse effects of cromolyn include sneezing, nasal stinging and burning, transient headache, and unpleasant aftertaste (Mygind, *et al.*, 1997).

2.2.2.4 Anticholinergics

Anticholinergic agents block cholinergic receptors on the nasal mucosa (Vogt, 1990), and control vasodilation and secretion of serous glands in the nasal mucosa, resulting in many unpleasant anticholinergic side effects commonly associated with cholinoceptor antagonists such as atropine. Adverse effects of these drugs include: impaired visual perception, decreased reaction time, decreased memory, and decreased coordination. In fact, in 1985, the Unites States Food and Drug Administration ruled that anticholinergics were not suitable for OTC distribution (Milgrom and Bender, 1997).

Ipratropium is a more recent anticholinergic drug initially released for treating chronic bronchitis and chronic obstructive lung disease. However its quaternary ammonia structure gives it high topical activity with no appreciable absorption across mucosal barriers, which results in fewer CNS related side effects encountered in previous drug regimes. Ipatropium bromide (Atrovent, Boehringer Ingelheim Pharmaceuticals, Ridgefield, CT) has been shown to be effective in the treatment of allergic rhinitis in children older than six years of age. Ipratropium decreases the watery rhinorrhoea and post-nasal drip in patients with allergic rhinitis, however it has no appreciable effect on sneezing, nasal obstruction, mucosal congestion, or modifying the allergic reaction (Vogt, 1990 and Weldon, 1998).

2.2.2.5 Decongestants

Decongestants are typically sympathomimetic drugs available in both oral and topical forms (Vogt, 1990). Decongestants constrict the blood vessels and counteract the effects of histamine (Paradox, 2001). A number of alpha-adrenergic agonists are commonly employed for oral use, including: phenypropanola-mine, phenylephrine and pseudoephedrine. These drugs primarily reduce nasal congestion, and to a small extent rhinorrhoea, but have no effect on sneezing, ocular symptoms, and itching. Therefore, they are only helpful in the treatment of allergic rhinitis when used in conjunction with antihistamines (Weldon, 1998 and Corren, 2000).

Oral decongestants are likely to create adverse systemic effects (Thornhill and Kelly, 2000). The most notable adverse effects of oral decongestants include: CNS symptoms such as irritability, nervousness, insomnia, headache, and cardiovascular symptoms such as palpitations and tachycardia. In addition, these drugs may raise intraocular pressure and blood pressure, and should be avoided in elderly patients and in patients with ischaemic heart disease, glaucoma and hyperthyroidism (Corren, 2000).

Topical intranasal preparations are widely used by patients suffering from allergic rhinitis and include the short-acting phenylephrine, and the longer acting naphazoline, xylometolazine, and oxymetolazine. Topical decongestants reduce airflow resistance by attenuating blood volume in the mucosa of the nose. However, when topical decongestants are used for more than three to five days, many of the patients will experience rebound congestion once the drug is discontinued. Thus these drugs are not effective for long term use because of the risk of rebound hyperaemia, mucosal damage, excrutiating pain in the nasal passages, and receptor desensitisation (Corren, 2000 and Thornhill and Kelly, 2000). Furthermore, if patients continue to use these medications over a period of several months, rhinitis medicamentosa will develop, which is difficult to treat effectively (Graf, 1997).

2.2.2.6 Antihistamine-Decongestant Combinations

One of the most popular OTC medications for allergic rhinitis is the combination of H1 antihistamine and a decongestant. Both the second-generation antihistamines, fexofenadine and loratadine are available in combination with long-acting pseudoephedrine, and provide better relief than does an antihistamine alone (Corren, 2000). Opthalmological decongestant and antihistamine medications offer relief to the itching and erythema of allergic conjunctivitis (Vogt, 1990).

2.2.2.7 Immunotherapy

Specific-allergen immunotherapy (allergy vaccine therapy) is the process of desensitization or hyposensitization using injections of extracted allergens, prophylactically, and is conventionally employed for the long-term management of allergic rhinitis (Paradox, 2001).

Immunotherapy is a treatment that attempts to increase the threshold level for symptoms appearing as a result of exposure to an aero-allergen. This altered degree of sensitivity may be as a result of either:

- A decrease in allergic antibody.
- The induction of a new antibody.
- A change in the cellular histamine release phenomenon,

or as a result of all three possibilities (Ricketti, 1997).

Immunotherapy aims to suppress IgE production, produce competitive immunoglobulin G (IgG) blocking antibodies, reduce sensitivity of basophils to allergens, and reduce lymphocyte responsiveness to allergens. Patients are not cured of their disease, but treatment rather aims to have fewer symptoms which are more easily controlled by symptomatic treatment (Poitevin, 1998).

Immunotherapy is considered in patients who:

- Do not respond to a combination of environmental control measures and medication.
- Have symptoms that affect them throughout the year.
- Experience severe adverse effects to medications.
- Prefer long-term modulation of their allergic symptoms (Corren, 2000).

It must be noted that immunotherapy based solely on positive findings on skin test or RASTs should not be expected to be beneficial (Ricketti, 1997).

The allergens used for immunotherapy should be those that cannot be avoided such as pollens, house dust mites, and moulds. The allergen extract is administered in gradually increasing doses aiming at altering the patient's immunological allergic response to the allergens, and reduce the harmful effects of contact with the allergen (Poitevin, 1998).

The efficacy of immunotherapy is questionable, as there is no adequate laboratory method to indicate how long a patient should receive immunotherapy, or any long-term clinical studies showing how patients fare after variable periods of therapy. This treatment frequently fails as patients find the process long and tedious, with slow results, and discontinue the injection programme because of dissatisfaction (Ricketti, 1997). There is also the risk of anaphylaxis and death, and as such, immunotherapy should only be administered in medical facilities that are equipped to handle such an emergency (American Academy of Allergy, Asthma and Immunology, 1994).

2.3 Natural Approach to Treating Allergic Rhinitis

Effective treatment aims to control symptoms by eliminating the environmental allergens where possible (Pharmacia Diagostics and Medical Specialities, 1987).

2.3.1 Elimination of Allergens

Allergen and irritant avoidance is frequently overlooked in the management of allergic rhinitis, although common sense dictates that patients should, in part, be capable of recognising the causative factors of their condition. It is a primary role of the physician to help patients who suffer from allergic rhinitis to acknowledge avoidance techniques, as they can significantly improve their quality of life with the use of environmental controls (Weldon, 1998).

The first rule in the management of the allergic patient is to identify through patient history and diagnostic tests the offending allergens (Pharmacia Diagnostics and Medical Specialities, 1987). Environmental control programmes should always be based on accurate assessments of both exposure and sensitisation to assess for patients who only suffer from perennial symptoms attributable to indoor allergens such as animal dander, cockroaches, house dust mites, indoor moulds, and occupational allergens, with no evidence of allergy to pollens or outdoor moulds. In these cases especially, allergen avoidance is a critical first step in treatment (Corren, 2000). If it is not possible to completely remove the offending allergen(s), focus the effort on lessening the exposure to the allergen(s) (Pharmacia Diagnostics and Medical Specialities, 1987).

2.3.2 Indoor Allergens

2.3.2.1 Animal Dander

Patients allergic to animal dander should give serious consideration to their health before adopting pets, and should keep exposure to animals to a minimum. If really necessary,

pets should be removed from the house, and not be allowed indoors. Where it is not possible to remove the animal, wash it weekly. Patients should also bear in mind that it may take several months after the removal of a pet from the house before they see any amelioration of their allergic rhinitis symptoms (Corren, 2000 and Potter and Buys, 2001).

2.3.2.2 Cockroach

Pesticide application is only temporarily effective, and the problem of cockroach infestation will recur unless food and garbage are packaged and handled appropriately (Gergen, *et al.*, 1999).

2.3.2.3 House Dust Mites

House dust mites are the commonest allergens along coastal areas of South Africa (Manjra, 2001). Studies have demonstrated that mite avoidance must be aggressive in order to be effective, and should include: encasing base and mattresses with impermeable zippered vinyl covers, washing of all bedding in hot water (>60 degrees Celsius), avoiding laying on carpeted surfaces or replacing carpets with tiles or hardwood floors, removing books, thick curtains and fluffy toys, and avoiding feather duvets and cushions. Additional benefits would be derived from frequent cleaning of carpets, curtains, floors, and bedclothes and mattresses using high quality vacuum cleaners equipped with double-reservoir bags and/ or high-efficiency particulate air filters (HEPA) (Corren, 2000, Weldon, 1998 and Manjra, 2001).

2.3.2.4 Indoor Mould

Moulds such as *Aspergillus, Alternaria, Cladosporium* and *Epicoccum* thrive in warm humid environments such as South Africa (Manjra, 2001). Identification of indoor mould is difficult, and in some instances only the presence of a musty smell and visual identification of mould confirm the problem. Limited measures to get rid of indoor

mould, such as the application of fungicides and bleach have not been shown to be effective. It is advisable to reduce indoor humidity, limit indoor plants, and to regularly clean shower curtains. In serious cases the only resort is to rebuild parts of the house (Manjra, 2001 and Corren, 2000).

2.3.2.5 Occupational Allergens

Where exposure to occupational allergens is the cause of allergic rhinitis, it is advisable to employ the use of protective clothing such as masks and gloves.

2.3.3 Outdoor Allergens

2.3.3.1 Pollen Allergy

Grass, weed, and tree pollens are a major problem along non-coastal areas of South Africa (Manjra, 2001). Patients who are allergic to pollen should avoid outdoor activities such as grass cutting and outdoor sports during peak pollination periods, keep their windows and doors closed during the spring and autumn seasons, and use indoor air-conditioning systems (Corren, 2000).

2.3.3.2 Outdoor Moulds

Mould sensitive patients should avoid raking of leaves, exposure to compost, contact with outdoor vegetation, and shady areas (Manjra, 2001).

2.3.4 Alternative Therapies

Alternative treatments, more often than not, focus on modulation of the body's immune response, and frequently centre round lifestyle adjustments and diet (Paradox, 2001).

2.3.4.1 Diet

For hay fever, naturopaths recommend a dietary plan as the first phase of treatment. A short initial fast is advocated, as it is believed most allergic reactions occur when the body is in a state of toxicity, usually as the result of high acidity. This is followed by a simple cleansing diet of fresh raw fruits followed by the introduction of fresh raw vegetables, both of which are alkaline. It is advised to cut out all refined sugars and carbohydrates in order to stabilise blood sugar levels for a time, as it is believed that people with high levels of histamine have a tendency to hypoglycaemia. It may also help to eliminate mucous-forming foods such as dairy products, citrus fruits, and wheat, and to reduce the intake of spicy and sour foods which may trigger inflammation (Evans, 1997).

2.3.4.2 Vitamins, Minerals and Supplements

At the approach of the hay fever season it is recommended that patients boost their intake of vitamin A, B-complex vitamins, vitamin C, vitamin E, zinc, magnesium, and selenium (Steven, 1999), as these vitamins are thought to be therapeutic in the treatment of allergic rhinitis. However, with the exception of vitamin C, it still remains to research to validate the efficacy of these supplements in the treatment of allergic rhinitis (Thornhill and Kelly, 2000). Bioflavinoids help reduce sensitivity, and it is advised to obtain as many of these as possible by eating a well-balanced diet rich in nutrients (Steven, 1999). In the case of severe symptoms, 2000 milligrams (mg) of vitamin C is recommended daily, to act as a natural anti-histamine (Evans, 1997). Vitamin C is non-toxic, and virtually free of side effects (Thornhill and Kelly, 2000). It has been found to exert a number of effects on histamine, and appears to prevent histamine secretion by white blood cells, and increase its detoxification (Murray, 1996).

2.3.5 Botanical Therapies

Natural therapies are safe, and may be used as primary therapy, or in conjunction with conventional methods (Thornhill and Kelly, 2000).

2.3.5.1 Herbalism

There are two herbs specifically useful in reducing the symptoms of hay fever, namely camomile (*Chamomilla recutita*) and eyebright (*Euphrasia officinalis*) which can both be ingested as a tea. However, for more severe cases an infusion of either of these herbs can be made by pouring boiling water over the leaves and flowers of the herb, and allowing the mixture to stand for ten minutes before straining the liquid for use. In cases with profuse watery mucous, alternative internal infusions may be made from, or with ground ivy (*Glechoma hederacea*) and/ or ribwort (*Plantago lanceolata*) (Evans, 1999).

2.3.5.2 *Urtica Dioica*

Urtica dioica is commonly referred to as stinging nettle. The fresh stinging hairs on the leaves of the nettle species contain concentrates of histamine, serotonin (5-hydroxytrytamine), and acetylcholine. While there is no known botanical counterpart whose inherent mechanism is the same as that of histamine, freeze-dried *Urtica dioica* works in ways similar to allopathic antihistamine (Thornhill and Kelly, 2000). A randomised, double-blind study in the efficacy of 300mg freeze-dried *Urtica dioica* in the treatment of allergic rhinitis found that the majority of the participants experienced relief of symptoms, and the study rated it higher than placebo in global assessments (Mittman, 1990). *Urtica dioica* offers symptomatic relief from sinusitis and other symptoms related to allergic rhinitis (Paradox, 2001). A 300mg dose of *Urtica dioica* once a day is recommended for the treatment of allergic rhinitis. No side effects have been reported, and because nettle leaf has a long history of use in food, it is considered to be safe (Zoorob and Morelli, 2002).

2.3.5.3 Bromelain

Bromelain is a proteolytic enzyme derived from the stem of the pineapple plant (*Ananas comosus*), and has been found to be an effective agent in respiratory tract disease (Thornhill and Kelly, 2000). The therapetical dose for the treatment of allergic rhinitis is 400-500mg three times a day (Kelly, 1996). However, allergic reactions may occur in individuals allergic to pineapple (Thornhill and Kelly, 2000).

2.3.5.4 Quercetin

Quercetin is a flavonoid of rutin, and is found in a wide variety of fresh herbs and vegetables. It inhibits the inflammatory processes caused by activated neutrophils (Thornhill and Kelly, 2000). A recent study of mast cells in Japan found that quercetin significantly inhibits antigen-stimulated histamine in patients suffering from allergic rhinitis (Otsuka, *et al.*, 1995). The recommended dosage for the treatment of allergic rhinitis ranges between 250-600mg, ten minutes before meals, three times a day (Guilliams, 1998). Quercetins efficacy is improved if bromelain is taken concomitantly (Taussig, 1980).

2.3.5.5 N-Acetylcysteine

N-acetylcysteine (NAC) is a naturally occurring amino acid derivative containing sulphur. While specific research on the use of NAC as a treatment for allergic rhinitis has not yet been undertaken, due to its affinity for mucous membranes and its because of its successful application in other respiratory diseases, it may fit the protocol of treatment for allergic rhinitis. Recommended therapeutical dosage ranges between 500mg to 2 gm daily (Thornhill and Kelly, 2000).

2.4 Homoeopathy

2.4.1 Overview

In recent years, a profound revolution in health has emerged. The concept of the whole man is replacing the previously fragmented view of the patient as merely a diagnostic entity. Arising from this trend is holistic healing which views each person as a unique individual. Homoeopathy epitomises holistic healing as it seeks to treat the individual, the root of disease, and to bring about cure by considering the totality of symptoms, namely mental, emotional and physical symptoms (Vithoulkas, 1985).

Homoeopathy is widely used throughout the world. A study of complimentary medicine conducted across Europe by Dr Peter Fisher, a consultant of the Royal London Homoeopathic Hospital, indicates that the practise of homoeopathy has become so commonplace it is virtually considered as orthodox. So much the case, that eighty to ninety-four percent of homoeopathic treatments are carried out by family doctors in France and Belgium. An astounding number of doctors, especially in North America and continental Europe, offer or refer patients to alternative therapies. Many physicians employ homoeopathy for the treatment of: hay fever (Steven, 1999), coryza, asthma, and many other disease conditions including: diarrhoea, migraine, and acute pain (D'Huyvetter and Cohrssen, 2002).

While there are still many dissidents who argue that homoeopathy does not work, or that homoeopathy is merely the placebo effect, there is a surpassing amount of clinical and laboratory information that has been published in support of homoeopathic remedies for asthma and hay fever (Ziment, 2000). A recent controlled clinical trial conducted on the efficacy of homoeopathically prepared *Allium cepa* in the treatment of hay fever found the remedy rated far more favourably than the placebo (Zoorob and Morelli, 2002). The existence of favourable findings for hay fever and asthma in double-blind, placebo-controlled studies of homoeopathic remedies disturbs orthodox physicians, but if one rejects publications that show favourable results for homoeopathy, one should be equally

sceptical of favourable outcomes in double-blind, placebo-controlled studies conducted on orthodox drugs (Ziment, 2000). The effects of homoeopathy can be long lasting, with nearly seventy-five percent of patients reporting marked or moderate improvements for up to a year after seeing an homoeopath (Attena *et al.*, 2000).

Allergic conditions generally respond well to homoeopathic treatment, and amazing results from a remedy given during an allergic attack are often seen (Morrison, 1998).

2.4.2 The History of Homoeopathy

Homoeopathy is not a new form of medicine (Master, 1992). The origins of homoeopathy date back to Hippocrates (460-350BC). Hippocrates was the first physician to treat patients by means of "similia" (similars) and "contraria" (contras) (Widakowich, 2000). Many great teachers in medicine, namely Hippocrates, Paracelsus, Stork, Holler and Galen, were familiar with the homoeopathic law of cure, but it was not until just under two hundred years ago that the visionary Dr Samuel Hahnemann, considered as the father of homoeopathy, postulated this law in 1810 (Master, 1992).

The term homoeopathy was coined by Dr Hahnemann, and is derived from the Greek words "homios" and "pathos", which mean similar affliction. This is the science of therapeutics based upon, and governed by the law of similars, *Similia Similibus Curentur*, which translates as "like cures like" (Boyd, 1989). Medication is prescribed according to the law of similars which states that any substance that produces disturbances and symptoms in an healthy person will cure those very same and similar symptoms when they appear in a sick person (Coulter, 1980 and Day, 1996).

2.4.3 Homoeopathic Pharmacy

Being a true scientist, Hahnemann tested this hypothesis exhaustively, and discovered that the theory was valid, but only when infinitesimal doses were used. He found that the more dilute he made his remedies, the more successful they became (Day, 1996). This process is known as potentization. Potentization can be defined as the mathematio-mechanical process for reduction, according to scale, of crude, inert substances (Master, 1992). It involves both the dilution and succussion of a substance. The substance is diluted with water and alcohol of varying percentages. Succussion is the process of shaking, by which the latent healing energy and medicinal value of the remedy is released (Hutchings and Hutchings, 1993).

The centissimal scale, used in this study makes reference to a dilution of 1:100, and is denoted by suffixing the letter "C", or "CH" to the number, thus indicating the potency (German Homoeopathic Pharmacopoeia, 1990). Based on the centissimal system of dilution, one part or the original undiluted substance is diluted in ninety-nine parts of the solvent so that the drug is reduced to one percent of its original concentration. This dilute is then succussed to result in the 1CH potency of the drug, with the "H" denoting the Hahnemannian method of potentization (D'Huyvetter and Cohrssen, 2002). The second potency is made by diluting one part of the 1CH solution with ninety-nine parts of the solvent followed by succussion, resulting in a potency of 2CH. Each consecutive potency is manufactured in the similar manner (Banerjee, 1991).

2.4.4 Homoeopathic Prescribing

Homoeopathic treatment usually includes symptomatic and constitutional remedies, and should include a remedy that acts on the emotional plane (Jouanny *et al.*, 1994).

There are two accepted methods of homoeopathic prescribing, acute (Clinical) and constitutional. These distinctions are artificial, but nevertheless useful. Naturally, any remedy can be either acute or constitutional (Morrison, 1998).

Clinical homoeopathy is acute prescribing based on clinical symptoms, and is employed to treat a single complaint or symptom, and is considered to be symptomatic and short acting. Often only an acute remedy can be found during the time of a crisis, and this prescription may need to be changed. This method of homoeopathy is employed especially by patients who self-medicate, and buy over the counter, symptom labelled specific drugs such as Natura's "Pharyna" for sore throat and post-nasal drip (Zoorob and Morelli, 2002).

Constitutional prescribing aims for long-term resolution of the problem. This is classical homoeopathy, in which a single, similimum remedy is prescribed with emphasis placed on unique, specifically individual symptoms experienced by the patient. In selecting the similimum remedy it is imperative to match the patient's clinical picture with the drug picture of the remedy that best fits it (Swayne, 1998). The better this totality is reflected in the therapeutic repertoire of the chosen remedy, the better the response in the patient. For the totality of symptoms to be cured, a potentized medicine must be sought which is proven to have the greatest tendency to produce closely similar symptoms in a physiological dose (Osawa, 2001).

2.4.5 Homoeopathic Aggravation

In some cases patients may experience an exacerbation of symptoms after taking a homoeopathic remedy. This is commonly referred to as a homoeopathic aggravation, which results in an initial worsening of the patients' symptoms. This phenomenon is more often witnessed in sensitive patients with an allergic predisposition. Hahnemann postulates that the medication must be naturally somewhat stronger than the ailment if it is to overpower and cure it. He also considered a homoeopathic aggravation to be a very good prognosis that the acute disease will most probably yield to the first dose (Hahnemann, 1998). In a recent study conducted in allergic rhinitis it was found that those patients who reported an initial aggravation were the ones who experienced the best response and outcome following the treatment (Taylor *et al.*, 2000).

2.4.6 *Sabadilla Officinarum*

2.4.6.1 Description of *Sabadilla Officinarum*

Sabadilla officinarum's botanical name is *Schoenocaulon officinale*. It is also known as *Veratrum officianale, Helonias officinalis* and *Asagraea officinalis*, but is most commonly referred to as Cevadilla seed (Varma and Vaid, 1997). It is a Mexican genus belonging to the *Colchicum* family *Melanthacea* (of the *Liliaceae*) (Clarke, 1977) that also occurs naturally in Guatemala, Venezuela, and the West Indies (Varma and Vaid, 1997).

It is an herbaceous plant, growing up to 1,5m in height. It has yellow flowers, linear, entire, tapering leaves, and bears fruit consisting of three slightly spreading brownish papery follicles. It has six seeds, 5 to 8mm in length, and up to 2mm in thickness, which are inodorous, but have a persistent acrid and bitter taste (Varma and Vaid, 1997).

2.4.6.2 *Sabadilla Officinarum* as a Homoeopathic Remedy

Homoeopathic provings (testing) were conducted on this remedy by leaders in the field of homoeopathy, including Hahnemann, Schultz, and Stapf (Hering, 1995). In potency, it is considered a specific remedy for hay fever. A tincture is made of the seeds, and then prepared according to homoeopathic procedure (Varma and Vaid, 1997).

2.4.6.3 Pathogenesis of *Sabadilla Officinarum*

In concentrated herbal form, such as a mother tincture, *Sabadilla officinarum* has an action on the mucous membranes of the nasopharynx and the lachrymal glands, resulting in violent acute inflammation (Kent, 1977, Varma and Vaid, 1997). The pathological action of this concentrated substance is to produce the hay fever-like symptoms of severe coryza, and hay fever-like symptoms such as spasmodic sneezing, redness of eyes, red, burning eyelids, lachrymation, and severe frontal pains (Boericke, 1929).

2.4.6.4 Mental Symptoms of *Sabadilla Officinarum*

The mental symptoms arising from *Sabadilla officinarum* in concentrated herbal form include: marked irritation, agitation, dislike of labour, great inclination to sleep during the daytime, and imperfect slumber in the evening (Kent, 1977 and Hering, 1995), intolerant of mental exertion, thinking results in a headache, sensation that articulation were suspended, sensation of constriction in the chest, and erroneous impressions as to the state of the body (Clarke, 1977). The patient may also have the delusion that he is sick (Allen, 2000).

2.4.6.5 Physical Symptoms of *Sabadilla Officinarum*

The primary physical symptom arising from *Sabadilla officinarum* in concentrated herbal form, is debilitating violent sneezing in spasmodic paroxysms of ten or more sneezes, with every sneeze provoking tears, worse for pollen (especially from flowers), open air, cold, early evening, odours, perfume, and in the morning (Morrison, 1998, Allan, 2000 and Hering, 1995). Other symptoms include: constant itching and tingling inside the nose, itching of the nasal alae and auditory meatus, nasal obstruction, generally thin copious watery discharge, often acrid, thick mucous, lachrymation, hot face, red, burning eyes, redness and burning of the eyelid margins, blue rings under the eyes, severe pain in the frontal sinuses, itching of the soft palate, dry, irritated cough, pharyngitis, throat symptoms that go from left to right, shortness of breath, great inclination to sleep during the day, imperfect sleep at night, and headache (Morrison, 1998 and Vermeulen, 1997).

In homoeopathy symptoms are considered in their complexity, and are called rubricks. The homoeopathic repertory is a text used by homoeopaths to gauge the effectiveness of a homoeopathic remedy for any given symptom (rubrick). For the purposes of this gradation, the efficacy a remedy for a symptom is represented by a numerical value of 1-4, with 4 denoting the most effective of the remedies, as proven clinically. Similarly, remedies are scored in the materia medica, using normal type, italics, and bold type,

which respectively denote the efficacy of the remedy for a symptom from the lesser to greatest. As per the Concordant Materia Medica (Vermeulen, 1997), *Sabadilla officinarum* scores as follows, for the relevant rubricks:

- VIOLENT OR ABORTIVE SNEEZING
- ITCHING IN THE NOSE
- *Spasmodic sneezing, coryza, and running nose*
- *Eyelids red, burning eyes, and lachrymation*
- *Formication*
- *Periodicity, same hour*
- Either nostril stuffed up
- Itching in ears
- Itching soft palate

2.4.6.6 Clinical Indications of *Sabadilla Officinarum*

Sabadilla officinarum in potency is clinically indicated primarily as an homoeopathic remedy for acute hay fever and coryza (Morrison, 1993 and Morrison, 1998), and is well indicated in allergic attacks displaying paroxysmal and periodic symptoms, be they in the springtime, every other day, fortnightly, or monthly (Clarke, 1977, Hering, 1995). It is also indicated for colds, cough, pharyngitis and asthma which occurs during general allergic and hay fever periods (Morrison, 1993).

For the treatment of hay fever using the homoeopathic remedy *Sabadilla officinarum,* the advocated dosage is the third to the thirtieth potency (Boericke, 1927 and Varna and Vaid, 1997). However, a higher potency is more effective in patients suffering from extreme mental symptoms during an hay fever attack.

The drug picture of *Sabadilla officinarum* matches the clinical picture of allergic rhinitis extremely well, and by using *Sabadilla officinarum,* the homoeopathic law, 'Similia Similibus Curentur', is applied, and the patient may potentially be homoeopathically cured.

CHAPTER THREE

METHODOLOGY

3.1 Materials Used

See Appendix F.

3.1.1 *Sabadilla officinarum 30CH and 200CH*

Natura (South Africa) supplied the *Sabadilla officinarum 30CH and 200CH* used in this trial.

3.2 Study Design

This study was designed as an one hour, double-blind, placebo-controlled trial, to test the efficacy of *Sabadilla officinarum 30CH* and *Sabadilla officinarum 200CH* in the treatment of allergic rhinitis. This study was motivated to take place in the natural setting, opposed to a clinical trial, as most sufferers of allergic rhinitis experience little or no relief from symptoms when taking medication (which is usually tested in a sterile setting, void of the everyday allergens the patient encounters daily). Out-patient treatment is considered particularly suitable for allergy monitoring by means of standard questionnaires which allows patients to record their experience with individual preparations in order to provide information about their effectiveness (Wiesenauer and Heidl, 1999).

3.3 Recruitment of Participants

Thirty participants of both sexes, over the age of eighteen, and with a history of allergic rhinitis, were randomly selected for this double-blind study. All participants were volunteers recruited by means of advertising posters and pamphlets posted and

distributed, with the necessary permission, at various healthcare facilities such as the Technikon Witwatersrand, doctors' rooms, and health stores.

3.4 Selection of Participants

Participants were required to complete an eligibility questionnaire (Appendix A). Inclusion criteria required participants to score a total symptom score (TSS) of greater than six, for two or more of the five symptom categories: rhinorrhoea (watery or runny nose), nose (congested or blocked or stuffy), sneezing, eyes (itchy and/ or watery and/ or red), and itchy nose and/ or palate and/ or throat and/ or ears. Excluded were patients who scored less than two of the five symptoms listed above.

Once the study had been fully explained, participants were required to complete consent forms (Appendix B). Each participant was furthermore required to complete a patient information form outlining personal data (Appendix C).

3.5 Research Procedure

Both the control group, consisting of ten participants, and the two experimental groups, consisting of ten participants each, were randomly selected from these participants. The patients were all supplied with:

- A single (stat) dose of medication to use at the time of an allergic rhinitis attack.
- A diary card (Appendix D) on which to score the severity of their symptoms at the time of such an attack.
- A response to treatment questionnaire (Appendix E) to fill in on the completion of their treatment.

The placebo, for the control group, consisted of unmedicated granules prepared in the form of ten powders. Lactose granules were impregnated with the homeopathic remedies, *Sabadilla officinarum 30CH* and *Sabadilla officinarum 200CH* , and prepared in the form of ten powders each. All medications were prepared by Dr S. van Es, using

Natura products, and packaged in the same manner, and labelled accordingly, with neither the patients, nor the researcher being aware of which remedy was being administered to whom.

In the first experimental group, each of the ten patients received one stat dose of *Sabadilla officinarum 30CH* in powder form. The ten patients constituting the second experimental group each received one stat dose of *Sabadilla officinarum 200CH* in powder form. The control group of ten patients each received one stat dose of unmedicated powder (placebo).

When suffering from an hay fever attack, the participants were instructed to score the severity of each of the five categories of allergic rhinitis symptoms on their individual diary cards (Appendix D) immediately before taking their medication, in order to assess time 0 (baseline).

The following five categories of symptoms were scored individually:

- Rhinorrhoea (watery or runny nose)
- Nose (congested or blocked or stuffy)
- Sneezing
- Eyes (itchy and/ or watery and/ or red)
- Itchy nose and/ or palate and/ or throat and/ or ears.

Severity of symptoms were evaluated according to the following scale:

- 0 = Absent
- 1 = Mild – Symptom is present, but not troublesome or annoying
- 2 = Moderate – Symptom is troublesome, but does not interfere with normal activity or sleep
- 3 = Severe – Symptom is troublesome enough to interfere with normal activity and/ or sleep
- 4 = Very Severe – Symptom is severe enough to warrant medication

(Potter and Schoeman, 2001).

The participants were then instructed to ingest their stat dose of medication by dissolving it sublinguually, and score the severity of their symptoms on their dairy card (Appendix D), using the same scale, at fifteen minute intervals, for sixty minutes thereafter (Potter and Schoeman, 2001). In addition, the patients were required to fill in the response to treatment questionnaire (Appendix E) on completion of their treatment.

3.6 Data Collection and Analysis

The diary cards (Appendix D) were collected from patients once they were completed. The categorizing data was collected using contingency tables, and the association between variables was observed by means of the Wilcoxon Signed Ranks Test and the Kruskal-Wallis Test. Analysis of variance for categorical data was conducted to ascertain the differences in the effects of the medications, and to determine any changes in the presenting symptoms, and the severity of the allergic rhinitis. The data from the eligibility questionnaires (Appendix A) and the response to treatment questionnaire was used for descriptive statistics. The success of the treatment will be based on the reduction of allergic rhinitis symptoms.

CHAPTER FOUR

RESULTS

4.1 Statistics Utilized

4.1.1 Overview

All the results obtained from the study were statistically analysed by means of the Wilcoxon Signed Rank Test, the Kruskal-Wallis Test, and making use of descriptive statistics. These non-parametric tests were used due to the fact that there were less than thirty participants in each group, and because they best reflect normality on such small sample groups.

As there were too many variables, namely the time intervals of zero, fifteen, thirty, forty-five, and sixty minutes, these were combined into intervals, namely initial versus first-half, initial versus second-half, and first-half versus second-half, to streamline and better reflect the data.

Statisticians at Rand Afrikaanse University analysed the data triple blind.

4.1.2 The Wilcoxon Signed Ranks Test

The Wilcoxon Signed Ranks Test is a nonparametric procedure used with two related variables. It tests the hypothesis that the two variables have the same distribution, but makes no assumptions about the shapes of the distributions of the two variables. This test takes information about the magnitude of differences within pairs into account, and gives more weight to pairs that show large differences than to pairs that show small differences. The Wilcoxon test statistic is based on the ranks of the absolute values of the differences between the two variables.

4.1.3 The Kruskal-Wallis Test

The Kruskal-Wallis Test is a nonparametric equivalent to one-way ANOVA. It tests whether several independent samples are from the same population, making the assumption that the underlying variable has a continuous distribution, and requires an ordinal level of measurement. The Kruskal-Wallis Test was used to determine whether there was an initial difference between the control group and the two experimental groups at the beginning of the study, in terms of the baseline (time 0) scores.

4.2 Testing of the Hypothesis

The null hypothesis stated that the mean for the two experimental groups equals the mean of the control group.

For every null hypothesis there has to be an alternative hypothesis. The alternative hypothesis stated that the mean for the two experimental groups does not equal to the mean of the control group.

4.2.1 The p-value

The 0,05 p-value (Sig) was employed, and indicates a ninety-five percent confidence level of the difference. If the p-value was less than 0,05 it would indicate that the group means of the control group and the two experimental groups were different at the start of the study, and the null hypothesis would be rejected. If the p-value was equal to or greater than 0,05 it would indicate that the group means of the control group and the two experimental groups were equal at the start of the study, and the null hypothesis would be accepted.

In some instances the 0,10 p-value was employed to highlight significant findings at a ninety percent confidence level of the difference.

Table 4.1 Summary of the Initial Differences Between Groups

Symptom	P-value of Baseline (0 mins)
Rhinorrhoea	0.875
Nose	0.216
Sneezing	0.193
Eyes	0.515
Itchiness	0.347

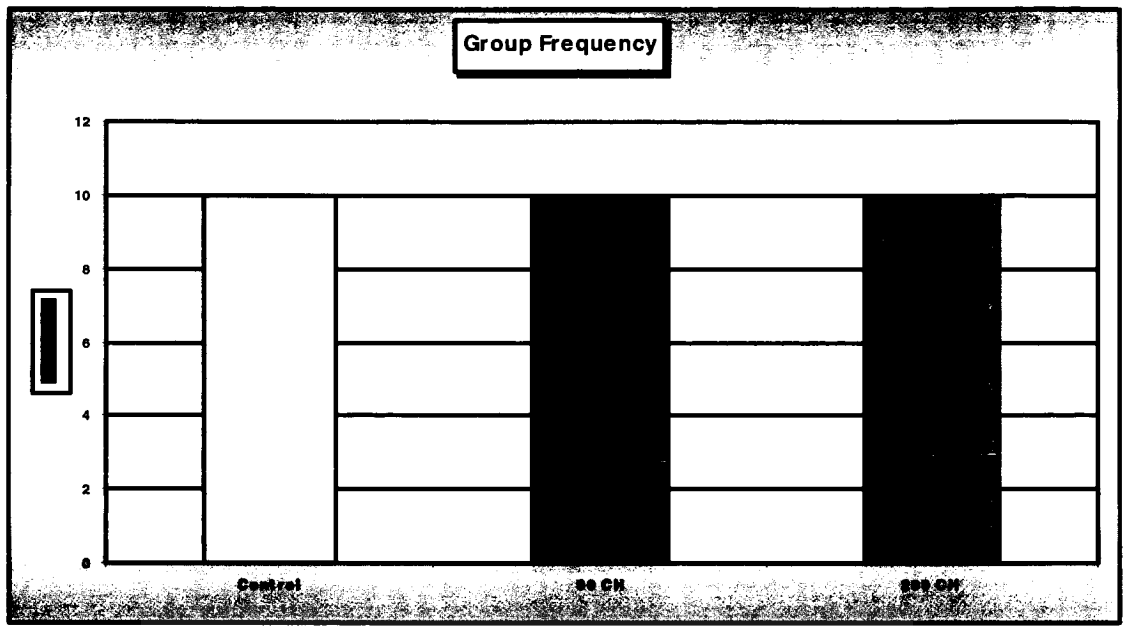
According to Table 4.1, the p-value was greater than 0,05 for all five symptoms, across all three groups. Therefore the null hypothesis was rejected, as the group means were the same, indicating no differences existed between the three groups at the start of the study, and that the groups were in fact similar. For the full statistical analysis from which this summary is derived, refer to Appendix G-1.

4.3 Analysis According to Frequency

4.3.1 Group Frequency

Thirty participants were randomly allocated into one of three groups, consisting of ten participants each, Group A, Group B, and Group C. Once the research was completed, it was determined from the relevant sources that group A was the control (placebo) group who received unmedicated powders. Group B was determined to be the first experimental group who received powders medicated with *Sabadilla officinarum 30CH.* Group C was determined to be the second experimental group who received powders medicated with *Sabadilla officinarum 200CH.* This data is illustrated in Figure 4.1.

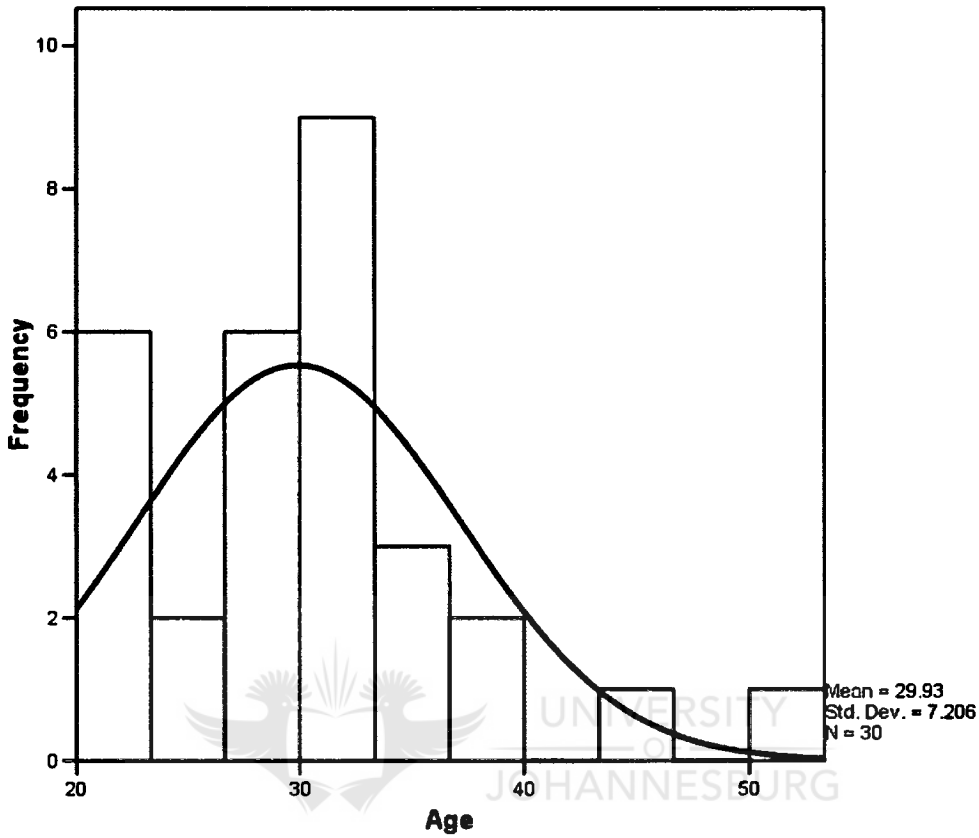
Figure 4.1 Illustrates Group Frequency



4.3.2 Age Frequency

Only participants over the age of eighteen were included in this study. The age of the participants was determined according to frequency as indicated in Figure 4.2.

Figure 4.2 Illustrates Age Frequency



The majority of participants recruited for this study fell between the ages of twenty-eight and thirty-one years. The mean age of the participants was thirty years as depicted in Table 4.2.

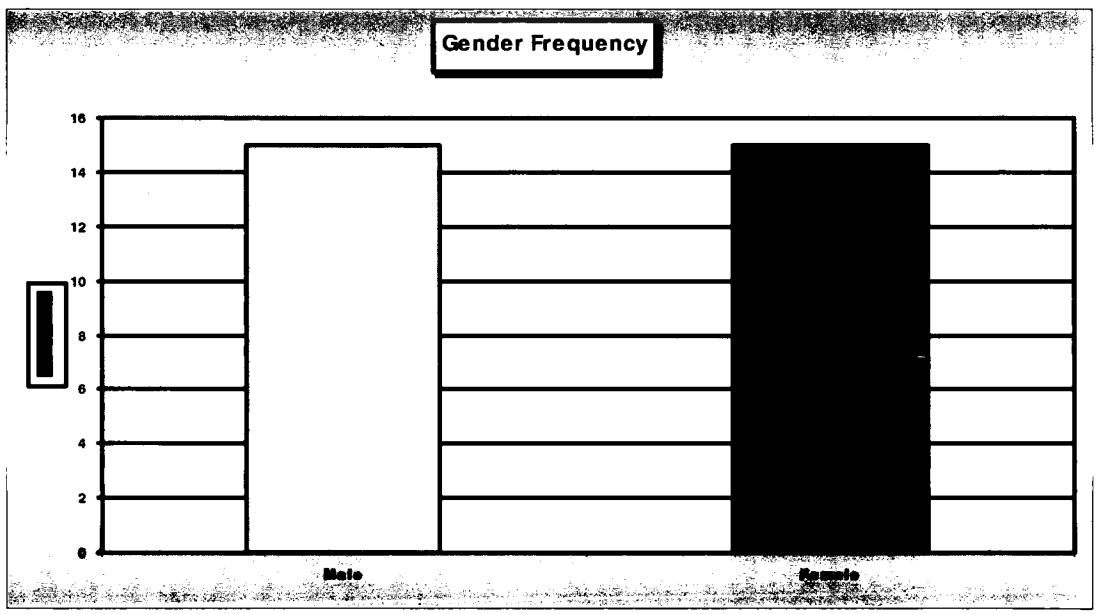
Table 4.2 Illustrates Mean Age

Age		
N	Valid	30
	Missing	0
Mean		29.93
Median		30.00
Std. Deviation		7.206
Minimum		20
Maximum		53

4.3.3 Gender Frequency

Both male and female participants were recruited for this study, and were represented equally as indicated in Figure 4.3.

Figure 4.3 Illustrates Gender Frequency



4.4 Data Obtained from Eligibility Questionnaire

Patients were required to complete an eligibility questionnaire (Appendix A) prior to their inclusion in the study. This data was obtained to determine the severity of symptoms, per symptom, experienced by the participants during a typical allergic rhinitis attack. Inclusion criteria required participants to score a total symptom score (TSS) of greater than six, for two or more of the five symptoms. Excluded were patients who scored less than two of the five symptoms.

The five categories of symptoms were scored individually using a scale of 0-5 to denote severity experienced.

All the participants included in the study scored a total symptom score (TSS) of greater than six, for two or more of the five symptom categories. Participants who had minor omissions in their dairy cards that did not prevent their analysis were not omitted from the study.

This data was obtained for the purpose of descriptive statistics, to determine:

- The severity of allergic rhinitis symptoms typically experienced by the participants.
- Whether participants had previously been diagnosed by a professional health practitioner as having allergic rhinitis.
- Whether participants suffer from other hay fever related symptoms.
- Whether participants are smokers or non-smokers.

Table 4.3 Severity of Allergic Rhinitis Symptoms Typically Experienced

		Mild	Moderate	Severe	Very severe	Total
Rhinorrhoea	**Count**	2	5	14	7	28
	Percent	7.1%	17.9%	50.0%	25.0%	100.0%
Nose	**Count**	1	4	16	4	25
	Percent	4.0%	16.0%	64.0%	16.0%	100.0%
Sneezing	**Count**	1	11	11	6	29
	Percent	3.4%	37.9%	37.9%	20.7%	100.0%
Eyes	**Count**	4	10	8	7	29
	Percent	13.8%	34.5%	27.6%	24.1%	100.0%
Itchiness	**Count**	2	8	8	7	25
	Percent	8.0%	32.0%	32.0%	28.0%	100.0%

As depicted in Table 4.3, the majority of participants typically experience moderate to very severe allergic rhinitis symptoms, with the vast majority of participants suffering from all five symptoms.

Despite the fact that all the participants, who completed the questionnaire completely, stated that they suffer from hay fever, only fifty-six percent had previously been diagnosed as hay fever sufferers by their medical practitioner, as illustrated in Table 4.4.

Table 4.4 Illustrates the Percentage of Previously Diagnosed Hay Fever

		Yes	No	Total
Suffer from hay fever	**Count**	29		29
	Percent	100.0%		100.0%
Previously been diagnosed as having hay fever	**Count**	15	12	27
	Percent	55.6%	44.4%	100.0%

Table 4.5 Hay Fever Related Symptoms

		Yes	No	Total
Hay fever symptoms last longer than an hour	**Count**	22	8	30
	Percent	73.3%	26.7%	100.0%
More than 10 sneezes in a row	**Count**	13	16	29
	Percent	44.8%	55.2%	100.0%
Mental symptoms	**Count**	19	10	29
	Percent	65.5%	34.5%	100.0%
Problems related to sleep	**Count**	13	15	28
	Percent	46.4%	53.6%	100.0%
Lower self-esteem	**Count**	6	22	28
	Percent	21.4%	78.6%	100.0%
Suffer from other allergies	**Count**	18	9	27
	Percent	66.7%	33.3%	100.0%

The participants were also required to comment on other hay fever related symptoms as illustrated in Table 4.5.

Table 4.6 Illustrates Percentage of Cigarette Smokers

		Yes	No	Total
Do you smoke	**Count**	12	17	29
	Percent	41.4%	58.6%	100.0%

The participants were also asked to report whether or not they were smokers. As illustrated in Table 4.6.

4.5 Data Obtained from Diary Card

When suffering from an hay fever attack, the participants were instructed to score the severity of each of the five categories of allergic rhinitis symptoms on their individual diary cards (Appendix D) immediately before taking their medication, in order to assess time 0 (baseline).

The five categories of symptoms were scored individually:

- Rhinorrhoea (watery or runny nose)
- Nose (congested or blocked or stuffy)
- Sneezing
- Eyes (itchy and/ or watery and/ or red)
- Itchy nose and/ or palate and/ or throat and/ or ears.

Severity of symptoms were evaluated according to the following scale:

- 0 = Absent
- 1 = Mild – Symptom is present, but not troublesome or annoying
- 2 = Moderate – Symptom is troublesome, but does not interfere with normal activity or sleep
- 3 = Severe – Symptom is troublesome enough to interfere with normal activity and/ or sleep
- 4 = Very Severe – Symptom is severe enough to warrant medication
  (Potter and Schoeman, 2001).

The participants then ingested their stat dose of medication by dissolving it under their tongue, and scored the severity of their symptoms, using the same scale, at fifteen minute intervals, for sixty minutes thereafter (Potter and Schoeman, 2001). This data was then statistically analysed per symptom.

4.5.1 Rhinorrhoea

Table 4.7 Control – Severity of Rhinorrhoea Symtoms Versus Time

Time		Symptom Absent	Symptom Mild	Symptom Moderate	Symptom Severe	Symptom Very severe	Total
0 mins	Count	1		3	2	4	10
	Percent	10.0%		30.0%	20.0%	40.0%	100.0%
15 mins	Count	1		4	2	3	10
	Percent	10.0%		40.0%	20.0%	30.0%	100.0%
30 mins	Count	1		4	4	1	10
	Percent	10.0%		40.0%	40.0%	10.0%	100.0%
45 mins	Count	1	1	5	2	1	10
	Percent	10.0%	10.0%	50.0%	20.0%	10.0%	100.0%
60 mins	Count	1	2	6	1		10
	Percent	10.0%	20.0%	60.0%	10.0%		100.0%

As depicted in Table 4.7, all ten participants in the control group reported on this symptom on the day of the study. Nine of the ten participants reported suffering from rhinorrhoea on the day.

Table 4.8 ***Sabadilla officinarum 30 CH*** **– Severity of Rhinorrhoea Versus Time**

Time		Symptom Absent	Symptom Mild	Symptom Moderate	Symptom Severe	Symptom Very severe	Total
0 mins	Count		1		5	2	8
	Percent		12.5%		62.5%	25.0%	100.0%
15 mins	Count	1	1	3	2	1	8
	Percent	12.5%	12.5%	37.5%	25.0%	12.5%	100.0%
30 mins	Count	2	3	2	1		8
	Percent	25.0%	37.5%	25.0%	12.5%		100.0%
45 mins	Count	2	3	1	2		8
	Percent	25.0%	37.5%	12.5%	25.0%		100.0%
60 mins	Count	4	2		1	1	8
	Percent	50.0%	25.0%		12.5%	12.5%	100.0%

As depicted in Table 4.8, eight of the ten participants in the *Sabadilla officinarum 30CH* group reported on this symptom on the day of the study. All eight of these participants reported suffering from rhinorrhoea on the day.

As the number in the group reporting on this symptom was less than ten participants, the zero values were excluded, since the values were calculated as averages, and should the zeros have been reflected in the calculations, it will have reduced the percentage improvement averages.

Table 4.9 ***Sabadilla officinarum 200 CH*** **– Severity of Rhinorrhoea Versus Time**

Time		Symptom Absent	Symptom Mild	Symptom Moderate	Symptom Severe	Symptom Very severe	Total
0 mins	Count		1	2	5	2	10
	Percent		10.0%	20.0%	50.0%	20.0%	100.0%
15 mins	Count		1	4	5		10
	Percent		10.0%	40.0%	50.0%		100.0%
30 mins	Count	1	3	3	3		10
	Percent	10.0%	30.0%	30.0%	30.0%		100.0%
45 mins	Count	2	3	5			10
	Percent	20.0%	30.0%	50.0%			100.0%
60 mins	Count	3	5	2			10
	Percent	30.0%	50.0%	20.0%			100.0%

As depicted in Table 4.9, all ten participants in the *Sabadilla officinarum 200CH* group reported on this symptom on the day of the study. All ten of these participants reported suffering from rhinorrhoea on the day.

Table 4.7, Table 4.8, and Table 4.9 indicate the overall improvement in the severity of the rhinorrhoea experienced by participants in all three groups during the hour-long study. The differences in these three groups are graphically represented in Figure 4.4, below.

Figure 4.4 Comparison of Percentage Improvement of Rhinorrhoea Between Groups

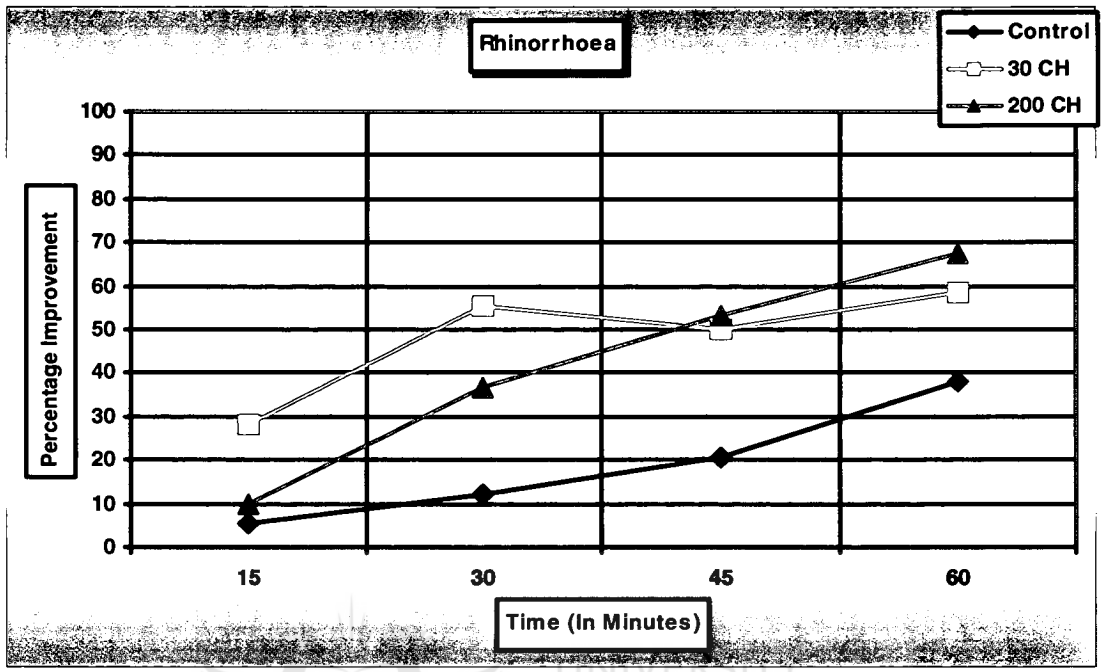


Figure 4.4 depicts the percentage of improvement of the rhinorrhoea over the hour of the study. The linear graph is used to make visualisation of the data easier by representing the range of data received. For the full statistical analysis from which this graph is derived refer to Appendix G-2.

Table 4.10 Rhinorrhoea - Summary of Differences Within Groups (P-value)

Rhinorrhoea - Summary of Differences Within Groups				
Intervals		**Control**	**30CH**	**200CH**
Initial vs First Half	0 mins (baseline) vs 30 mins	**0.059**	0.017	0.034
Initial vs Second Half	0 mins (baseline) vs 60 mins	0.011	0.027	0.007
First Half vs Second Half	30 mins vs 60 mins	0.010	0.443	0.007

In terms of the significant differences, p-values of 0,05 are indicated in red, and p-values of 0,10 are indicated in blue. These statistics were derived by means of the Wilcoxon

Signed Ranks Test. For the full statistical analysis from which this summary is derived, refer to Appendix G-3.

4.5.1.1 Group A – Control

As illustrated in Figure 4.4, the control group displayed little improvement of the rhinorrhoea symptom over the hour of the study, with only a thirty-eight percent improvement in symptom severity.

As depicted in Table 4.10, the p-value is more than 0,05, but less that 0,10 at thirty minutes, indicating little change in the first thirty minutes. The p-value less than 0,05 at the initial versus first-half interval indicates a moderate statistical change in the last half hour.

4.5.1.2 Group B – *Sabadilla officinarum 30CH*

As illustrated in Figure 4.4, the group receiving *Sabadilla officinarum 30CH* displayed a sixty percent improvement of the rhinorrhoea symptom over the hour of the study.

As depicted in Table 4.10, the p-value is less that 0,05 at the initial versus first-half, and initial versus second-half intervals, indicating a significant statistical improvement over the hour of the study. However the p-value is greater than 0,05 at the first-half versus second-half interval, indicating little change over the last half hour.

4.5.1.3 Group C – *Sabadilla officinarum 200CH*

As illustrated in Figure 4.4, the group receiving *Sabadilla officinarum 200CH* displayed a sixty-eight percent improvement of the rhinorrhoea symptom over the hour of the study.

As depicted in Table 4.10, the p-value is less that 0,05 over the entire sixty minutes of the study. The significant differences at the three intervals minutes indicate a continuous statistical improvement over the hour of the study.

4.5.1.4 Comparative Group Results of Rhinorrhoea

The control group showed no significant improvement, and is consistent with the placebo effect displayed in anti-histamine studies, which can be quite high (Potter *et al.*, 2001). However, both the experimental groups showed significant improvement.

At thirty minutes, the group receiving *Sabadilla officinarum 30CH* displayed the greatest improvement. However, its effect remained constant for the remaining half hour, with a slight aggravation at forty-five minutes, and little improvement at sixty minutes.

The group receiving *Sabadilla officinarum 200CH* proved to be most effective, displaying a marked improvement over the entire hour of the study, with the greatest percentage improvement overall.

4.5.2 Nasal Congestion

Table 4.11 Control – Severity of Nasal Congestion Versus Time

Time		Symptom Absent	Symptom Mild	Symptom Moderate	Symptom Severe	Symptom Very severe	Total
0 mins	Count	4	1	2	2	1	10
	Percent	40.0%	10.0%	20.0%	20.0%	10.0%	100.0%
15 mins	Count	4	1	3	2		10
	Percent	40.0%	10.0%	30.0%	20.0%		100.0%
30 mins	Count	5	1	2	2		10
	Percent	50.0%	10.0%	20.0%	20.0%		100.0%
45 mins	Count	5	4	1			10
	Percent	50.0%	40.0%	10.0%			100.0%
60 mins	Count	6	3		1		10
	Percent	60.0%	30.0%		10.0%		100.0%

As depicted in Table 4.11, all ten participants in the control group reported on this symptom on the day of the study. Six of these participants reported suffering from nose symptoms on the day.

Table 4.12 *Sabadilla officinarum 30CH* – Severity of Nasal Congestion Versus Time

Time		Symptom Absent	Symptom Mild	Symptom Moderate	Symptom Severe	Symptom Very severe	Total
0 mins	Count	1		2	5	1	9
	Percent	11.1%		22.2%	55.6%	11.1%	100.0%
15 mins	Count	2		3	3	1	9
	Percent	22.2%		33.3%	33.3%	11.1%	100.0%
30 mins	Count	2	2	4	1		9
	Percent	22.2%	22.2%	44.4%	11.1%		100.0%
45 mins	Count	3	3	2	1		9
	Percent	33.3%	33.3%	22.2%	11.1%		100.0%
60 mins	Count	3	5		1		9
	Percent	33.3%	55.6%		11.1%		100.0%

As depicted in Table 4.12, nine of the ten participants in the *Sabadilla officinarum 30CH* group reported on this symptom on the day of the study. Eight of these participants reported suffering from nose symptoms on the day.

As the number in the group reporting on this symptom was less than ten participants, the zero values were excluded, since the values were calculated as averages, and should the zeros have been reflected in the calculations, it will have reduced the percentage improvement averages.

Table 4.13 *Sabadilla officinarum 200CH* – Severity of Nasal Congestion Versus Time

Time		Symptom Absent	Symptom Mild	Symptom Moderate	Symptom Severe	Symptom Very severe	Total
0 mins	Count	3	1	3	2	1	10
	Percent	30.0%	10.0%	30.0%	20.0%	10.0%	100.0%
15 mins	Count	3	2	3	1	1	10
	Percent	30.0%	20.0%	30.0%	10.0%	10.0%	100.0%
30 mins	Count	2	3	3	2		10
	Percent	20.0%	30.0%	30.0%	20.0%		100.0%
45 mins	Count	3	2	4	1		10
	Percent	30.0%	20.0%	40.0%	10.0%		100.0%
60 mins	Count	3	4	3			10
	Percent	30.0%	40.0%	30.0%			100.0%

As depicted in Table 4.13, all ten participants in the *Sabadilla officinarum 200CH* group reported on this symptom on the day of the study. Seven of these participants reported suffering from nose symptoms on the day.

Table 4.11, Table 4.12, and Table 4.13 indicate the overall improvement in the severity of the nasal congestion experienced by participants in all three groups during the hour-long study. The differences in these three groups are graphically represented in Figure 4.5, below.

Figure 4.5 Comparison of Percentage Improvement of Nasal Congestion Between Groups

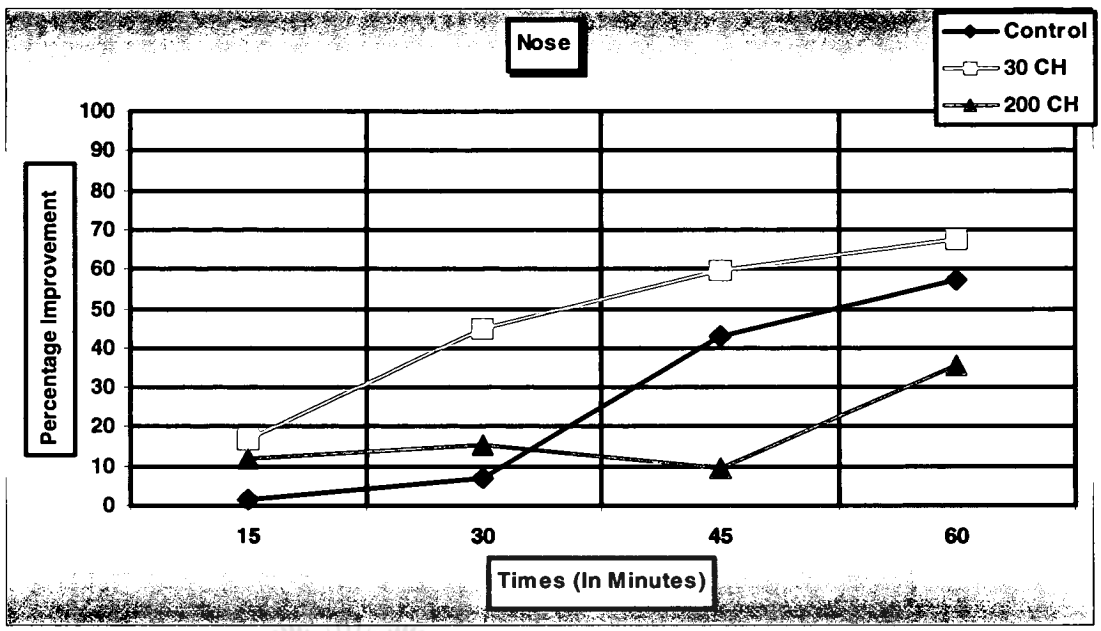


Figure 4.5 depicts the percentage of improvement of the nose symptoms over the hour of the study. The linear graph is used to make visualisation of the data easier by representing the range of data received. For the full statistical analysis from which this graph is derived refer to Appendix G-2.

Table 4.14 Nasal Congestion - Summary of Differences Within Groups (P-value)

Summary of Differences Within Groups				
Intervals		**Control**	**30CH**	**200CH**
Initial vs First Half	0 mins (baseline) vs 30 mins	0.290	0.008	0.194
Initial vs Second Half	0 mins (baseline) vs 60 mins	0.044	0.011	**0.071**
First Half vs Second Half	30 mins vs 60 mins	0.026	0.016	**0.084**

In terms of the significant differences, p-values of 0,05 are indicated in red, and p-values of 0,10 are indicated in blue. These statistics were derived by means of the Wilcoxon Signed Ranks Test. For the full statistical analysis from which this summary is derived, refer to Appendix G-3.

4.5.2.1 Group A – Control

As illustrated in Figure 4.5, the control group displayed little improvement of the nasal congestion at fifteen and thirty minutes, but showed a fifty-eight percent improvement by sixty minutes.

As depicted in Table 4.14, the p-value is greater than 0,05 at the initial versus first-half interval, indicating minimal change in the first thirty minutes. The p-value less than 0,05 at the initial versus second-half, and first-half versus second-half intervals, indicates a significant statistical change in the last half hour.

4.5.2.2 Group B – *Sabadilla officinarum 30CH*

As illustrated in Figure 4.5, the group receiving *Sabadilla officinarum 30CH* displayed a sixty-eight percent improvement of nasal congestion over the hour of the study.

As depicted in Table 4.14, the p-value is less that 0,05 at all three intervals, indicates a significant statistical improvement over the entire hour of the study.

4.5.2.3 Group C – *Sabadilla officinarum 200CH*

As illustrated in Figure 4.5, the group receiving *Sabadilla officinarum 200CH* displayed little or no improvement until forty minutes, with a thirty-six percent improvement at the end of the hour-long study.

As depicted in Table 4.14, the p-value is greater that 0,05 at the initial versus first-half interval, indicating little statistical change in this period. And, the p-value is at the ninety percent confidence level of less than 0,10 for the remainder of the hour, indicating positive statistical differences.

4.5.2.4 Comparative Group Results of Nasal Congestion

The control group showed an improvement of fifty-eight percent.

Of the two experimental groups, only the group receiving *Sabadilla officinarum 30CH* displayed a major change, with a marked improvement over the entire hour of the study, proving to be the most effective of the three groups, with the greatest percentage improvement overall.

The group receiving *Sabadilla officinarum 200CH* proved to be least effective. There was little change in the first thirty minutes, and a possible aggravation at forty minutes, before any significant improvement at sixty minutes.

4.5.3 Sneezing

Table 4.15 Control – Severity of Sneezing Versus Time

Time		Symptom Absent	Symptom Mild	Symptom Moderate	Symptom Severe	Symptom Very severe	Total
0 mins	Count			2	4	4	10
	Percent			20.0%	40.0%	40.0%	100.0%
15 mins	Count	1		3	6		10
	Percent	10.0%		30.0%	60.0%		100.0%
30 mins	Count		2	7	1		10
	Percent		20.0%	70.0%	10.0%		100.0%
45 mins	Count	2	4	4			10
	Percent	20.0%	40.0%	40.0%			100.0%
60 mins	Count	4	4	2			10
	Percent	40.0%	40.0%	20.0%			100.0%

As depicted in Table 4.15, all ten participants in the control group reported on this symptom on the day of the study. All ten of these participants reported suffering from sneezing on the day.

Table 4.16 *Sabadilla officinarum 30CH* – Severity of Sneezing Versus Time

Time		Symptom Absent	Symptom Mild	Symptom Moderate	Symptom Severe	Symptom Very severe	Total
0 mins	Count		1		3	4	8
	Percent		12.5%		37.5%	50.0%	100.0%
15 mins	Count	2	1	2	2	1	8
	Percent	25.0%	12.5%	25.0%	25.0%	12.5%	100.0%
30 mins	Count	4	1	2	1		8
	Percent	50.0%	12.5%	25.0%	12.5%		100.0%
45 mins	Count	5	1	1	1		8
	Percent	62.5%	12.5%	12.5%	12.5%		100.0%
60 mins	Count	5	2	1			8
	Percent	62.5%	25.0%	12.5%			100.0%

As depicted in Table 4.16, eight of the ten participants in the *Sabadilla officinarum 30CH* group reported on this symptom on the day of the study. All eight of these participants reported suffering from sneezing on the day.

As the number in the group reporting on this symptom was less than ten participants, the zero values were excluded, since the values were calculated as averages, and should the zeros have been reflected in the calculations, it will have reduced the percentage improvement averages.

Table 4.17 *Sabadilla officinarum 200CH* – Severity of Sneezing Versus Time

Time		Symptom Absent	Symptom Mild	Symptom Moderate	Symptom Severe	Symptom Very severe	Total
0 mins	Count		2	3	3	2	10
	Percent		20.0%	30.0%	30.0%	20.0%	100.0%
15 mins	Count	2	6	1		1	10
	Percent	20.0%	60.0%	10.0%		10.0%	100.0%
30 mins	Count	6	2	1		1	10
	Percent	60.0%	20.0%	10.0%		10.0%	100.0%
45 mins	Count	7	1		2		10
	Percent	70.0%	10.0%		20.0%		100.0%
60 mins	Count	8		1	1		10
	Percent	80.0%		10.0%	10.0%		100.0%

As depicted in Table 4.17, all ten participants in the *Sabadilla officinarum 200CH* group reported on this symptom on the day of the study. All ten of these participants reported suffering from sneezing on the day.

Table 4.15, Table 4.16, and Table 4.17 indicate the overall improvement in the severity of the sneezing experienced by participants in all three groups during the hour-long study. The differences in these three groups are graphically represented in Figure 4.6, below.

Figure 4.6 Comparison of Percentage Improvement of Sneezing Between Groups

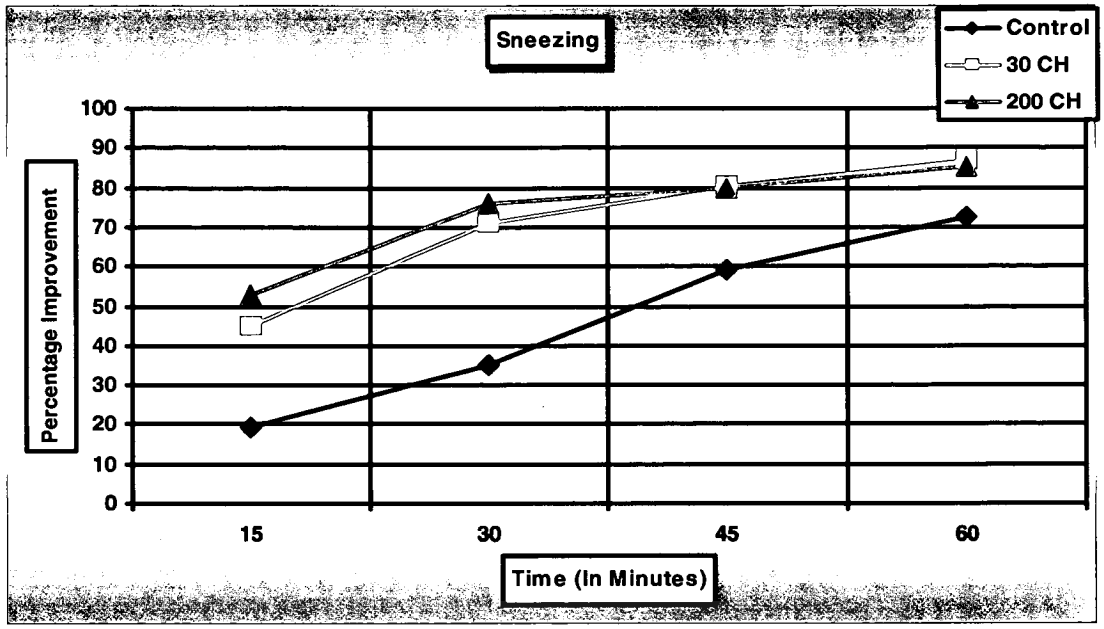


Figure 4.6 depicts the percentage of improvement of the sneezing over the hour of the study. The linear graph is used to make visualisation of the data easier by representing the range of data received. For the full statistical analysis from which this graph is derived refer to Appendix G-2.

Table 4.18 Sneezing - Summary of Differences Within Groups (P-value)

Summary of Differences Within Groups				
Intervals		Control	30CH	200CH
Initial vs First Half	0 mins (baseline) vs 30 mins	0.020	0.011	0.007
Initial vs Second Half	0 mins (baseline) vs 60 mins	0.005	0.012	0.007
First Half vs Second Half	30 mins vs 60 mins	0.011	**0.093**	**0.098**

In terms of the significant differences, p-values of 0,05 are indicated in red, and p-values of 0,10 are indicated in blue. These statistics were derived by means of the Wilcoxon Signed Ranks Test. For the full statistical analysis from which this summary is derived, refer to Appendix G-3.

4.5.3.1 Group A – Control

As illustrated in Figure 4.6, the control group displayed a gradual improvement over the fifteen-minute intervals, with a seventy-two percent improvement of sneezing by the end of the study.

As depicted in Table 4.18, the p-value is less than 0,05 between all three measured stages, indicating a substantial statistical change in the hour of the study.

4.5.3.2 Group B – *Sabadilla officinarum 30CH*

As illustrated in Figure 4.6, the group receiving *Sabadilla officinarum 30CH* displayed a major percent improvement of the sneezing over the hour of the study.

As depicted in Table 4.18, the p-value is less that 0,05 at the initial versus first-half, and initial versus second-half intervals, indicating a significant statistical improvement in the first half of the study. The p-value is only less than 0,10 at the first-half versus the second-half interval, indicating a less significant, but nonetheless statistical change over the last half hour.

4.5.3.3 Group C – *Sabadilla officinarum 200CH*

As illustrated in Figure 4.6, the group receiving *Sabadilla officinarum 200CH* displayed a major improvement in sneezing over the hour of the study.

As depicted in Table 4.18, the p-value is less that 0,05 at the initial versus first-half, and initial versus second-half intervals, indicating a significant statistical improvement in the first half of the study. The p-value is only at a ninety percent confidence level at the first-half versus the second-half interval, indicating a less significant, but nonetheless statistical change over the last half hour.

4.5.3.4 Comparative Group Results of Sneezing

The control group showed a considerable improvement.

However, both the experimental groups showed a more rapid onset of action, and a more marked improvement than the control group.

The results for both *Sabadilla officinarum 30CH* and *Sabadilla officinarum 200CH* are very similar, with both potencies displaying a major improvement very early in the study. Although the group receiving *Sabadilla officinarum 200CH* showed slightly more improvement at both fifteen and thirty minutes, the results for both potencies are in the high eighty percent range at the end of the hour-long study.

4.5.4 Ocular Symptoms

Table 4.19 Control – Severity of Ocular Symptoms Versus Time

Time		Symptom Absent	Symptom Mild	Symptom Moderate	Symptom Severe	Symptom Very severe	Total
0 mins	Count	1	3	3	1	2	10
	Percent	10.0%	30.0%	30.0%	10.0%	20.0%	100.0%
15 mins	Count	3	2	3	1	1	10
	Percent	30.0%	20.0%	30.0%	10.0%	10.0%	100.0%
30 mins	Count	3	1	4	2		10
	Percent	30.0%	10.0%	40.0%	20.0%		100.0%
45 mins	Count	5	2	2	1		10
	Percent	50.0%	20.0%	20.0%	10.0%		100.0%
60 mins	Count	4	4	2			10
	Percent	40.0%	40.0%	20.0%			100.0%

As depicted in Table 4.19, all ten participants in the control group reported on this symptom on the day of the study. Nine of these participants reported suffering from ocular symptoms on the day.

Table 4.20 ***Sabadilla officinarum 30CH*** **– Severity of Ocular Symptoms Versus Time**

Time		Symptom Absent	Symptom Mild	Symptom Moderate	Symptom Severe	Symptom Very severe	Total
0 mins	Count	1		3	4	2	10
	Percent	10.0%		30.0%	40.0%	20.0%	100.0%
15 mins	Count	1	2	2	4	1	10
	Percent	10.0%	20.0%	20.0%	40.0%	10.0%	100.0%
30 mins	Count	2	4	3	1		10
	Percent	20.0%	40.0%	30.0%	10.0%		100.0%
45 mins	Count	5	1	3	1		10
	Percent	50.0%	10.0%	30.0%	10.0%		100.0%
60 mins	Count	6	1	2	1		10
	Percent	60.0%	10.0%	20.0%	10.0%		100.0%

As depicted in Table 4.20, all ten participants in the *Sabadilla officinarum 30CH* group reported on this symptom on the day of the study. Nine of these participants reported suffering from ocular symptoms on the day.

Table 4.21 *Sabadilla officinarum 200CH* – Severity of Ocular Symptoms Versus Time

Time		Symptom Absent	Symptom Mild	Symptom Moderate	Symptom Severe	Symptom Very severe	Total
0 mins	Count	2		2	5	1	10
	Percent	20.0%		20.0%	50.0%	10.0%	100.0%
15 mins	Count	2	1	4	2	1	10
	Percent	20.0%	10.0%	40.0%	20.0%	10.0%	100.0%
30 mins	Count	2	6		1	1	10
	Percent	20.0%	60.0%		10.0%	10.0%	100.0%
45 mins	Count	4	4	1		1	10
	Percent	40.0%	40.0%	10.0%		10.0%	100.0%
60 mins	Count	6	2	1		1	10
	Percent	60.0%	20.0%	10.0%		10.0%	100.0%

As depicted in Table 4.21, all ten participants in the *Sabadilla officinarum 200CH* group reported on this symptom on the day of the study. Eight of these participants reported suffering from ocular symptoms on the day.

Table 4.19, Table 4.20, and Table 4.21 indicate the overall improvement in the severity of the ocular symptoms experienced by participants in all three groups during the hour-long study. The differences in these three groups are graphically represented in Figure 4.7, below.

Figure 4.7 Comparison of Percentage Improvement of Ocular Symptoms Between Groups

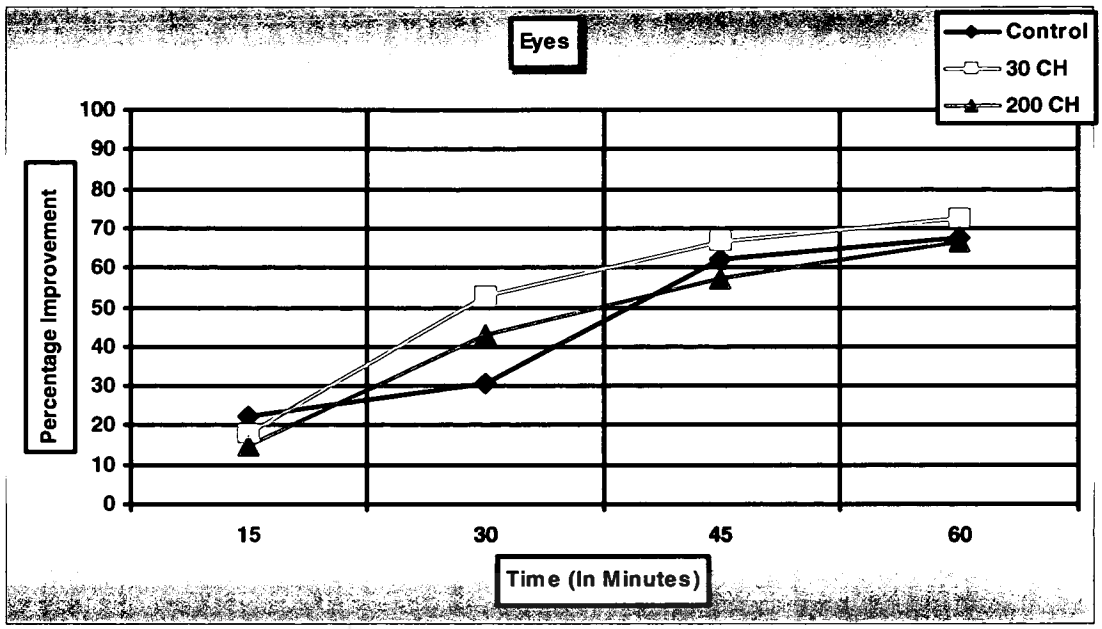


Figure 4.4 depicts the percentage of improvement of the ocular symptoms over the hour of the study. The linear graph is used to make visualisation of the data easier by representing the range of data received. For the full statistical analysis from which this graph is derived refer to Appendix G-2.

Table 4.22 Ocular Symptoms - Summary of Differences Within Groups (P-value)

Summary of Differences Within Groups				
Intervals		Control	30CH	200CH
Initial vs First Half	0 mins (baseline) vs 30 mins	**0.066**	0.007	**0.075**
Initial vs Second Half	0 mins (baseline) vs 60 mins	0.006	0.010	0.020
First Half vs Second Half	30 mins vs 60 mins	0.009	0.049	0.014

In terms of the significant differences, p-values of 0,05 are indicated in red, and p-values of 0,10 are indicated in blue. These statistics were derived by means of the Wilcoxon Signed Ranks Test. For the full statistical analysis from which this summary is derived, refer to Appendix G-3.

4.5.4.1 Group A – Control

As illustrated in Figure 4.7, the control group displayed little improvement of the ocular symptoms in the first half of the study. An improvement is noted between thirty and forty-five minutes, with little improvement thereafter.

As depicted in Table 4.22, the p-value is greater than 0,05, but less than 0,10 at the initial versus first-half interval, indicating little statistical change during that period. The p-value at the other two intervals is less than 0,05 indicating a substantial statistical change in the second half of the study.

4.5.4.2 Group B – *Sabadilla officinarum 30CH*

As illustrated in Figure 4.7, the group receiving *Sabadilla officinarum 30CH* displayed a fifty percent improvement of ocular symptoms by thirty minutes, and steadily improved to seventy-three percent by sixty minutes.

As depicted in Table 4.22, the p-value is less that 0,05 at all intervals over the course of the hour, indicating a significant statistical improvement.

4.5.4.3 Group C – *Sabadilla officinarum 200CH*

As illustrated in Figure 4.7, the group receiving *Sabadilla officinarum 200CH* displayed a significant improvement in ocular symptoms, with a sixty-seven percent improvement noted at the end of the hour.

As depicted in Table 4.22, the p-value is greater than 0,05 at thirty minutes, but less than 0,10, nonetheless indicating some significant improvement in the first half of the study. The p-value is less than 0,05 at the initial versus second-half, and first-half versus second-half intervals, indicating significant statistical change over the last thirty minutes.

4.5.4.4 Comparative Group Results of Ocular Symptoms

All three groups showed a considerable improvement.

However, both the experimental groups, especially the group which received *Sabadilla officinarum 30CH*, showed a more rapid onset of action.

4.5.5 Pruritis of the Ears, Nose and Throat (ENT)

Table 4.23 Control – Severity of ENT Pruritis Versus Time

Time		Symptom Absent	Symptom Mild	Symptom Moderate	Symptom Severe	Symptom Very severe	Total
0 mins	Count	2	3	3		2	10
	Percent	20.0%	30.0%	30.0%		20.0%	100.0%
15 mins	Count	2	2	4	2		10
	Percent	20.0%	20.0%	40.0%	20.0%		100.0%
30 mins	Count	4	1	4	1		10
	Percent	40.0%	10.0%	40.0%	10.0%		100.0%
45 mins	Count	4	4	2			10
	Percent	40.0%	40.0%	20.0%			100.0%
60 mins	Count	5	4	1			10
	Percent	50.0%	40.0%	10.0%			100.0%

As depicted in Table 4.23, all ten participants in the control group reported on this symptom on the day of the study. Eight of these participants reported suffering from ENT pruritis symptoms on the day.

Table 4.24 *Sabadilla officinarum 30CH* – Severity of ENT Pruritis Versus Time

Time		Symptom Absent	Symptom Mild	Symptom Moderate	Symptom Severe	Symptom Very severe	Total
0 mins	Count	1	1	1	4	1	8
	Percent	12.5%	12.5%	12.5%	50.0%	12.5%	100.0%
15 mins	Count	1	2	1	3	1	8
	Percent	12.5%	25.0%	12.5%	37.5%	12.5%	100.0%
30 mins	Count	2	1	4	1		8
	Percent	25.0%	12.5%	50.0%	12.5%		100.0%
45 mins	Count	3	1	4			8
	Percent	37.5%	12.5%	50.0%			100.0%
60 mins	Count	3	2	3			8
	Percent	37.5%	25.0%	37.5%			100.0%

As depicted in Table 4.24, eight of the ten participants in the *Sabadilla officinarum 30CH* group reported on this symptom on the day of the study. Seven of these participants reported suffering from ENT pruritis on the day.

As the number in the group reporting on this symptom was less than ten participants, the zero values were excluded, since the values were calculated as averages, and should the zeros have been reflected in the calculations, it will have reduced the percentage improvement averages.

Table 4.25 *Sabadilla officinarum 200CH* – Severity of ENT Pruritis Versus Time

Time		Symptom Absent	Symptom Mild	Symptom Moderate	Symptom Severe	Symptom Very Severe	Total
0 mins	Count	3	2	2	3		10
	Percent	30.0%	20.0%	20.0%	30.0%		100.0%
15 mins	Count	3	3	1	3		10
	Percent	30.0%	30.0%	10.0%	30.0%		100.0%
30 mins	Count	3	3	2	2		10
	Percent	30.0%	30.0%	20.0%	20.0%		100.0%
45 mins	Count	5	3		2		10
	Percent	50.0%	30.0%		20.0%		100.0%
60 mins	Count	6	2	1	1		10
	Percent	60.0%	20.0%	10.0%	10.0%		100.0%

As depicted in Table 4.25, all ten participants in the *Sabadilla officinarum 200CH* group reported on this symptom on the day of the study. Seven of these participants reported suffering from ENT pruritis on the day.

Table 4.23, Table 4.24, and Table 4.25 indicate the overall improvement in the severity of the ENT pruritis experienced by participants in all three groups during the hour-long study. The differences in these three groups are graphically represented in Figure 4.8, below.

Figure 4.8 Comparison of Percentage Improvement of ENT Pruritis Between Groups

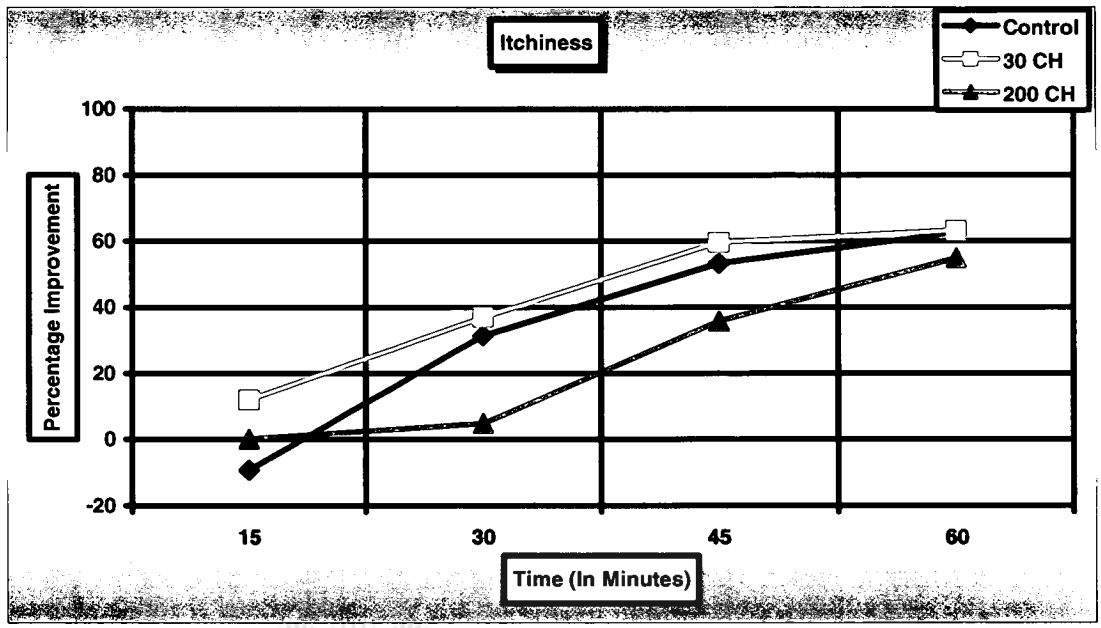


Figure 4.8 depicts the percentage of improvement of the ENT pruritis over the hour of the study. The linear graph is used to make visualisation of the data easier by representing the range of data received. For the full statistical analysis from which this graph is derived refer to Appendix G-2.

Table 4.26 ENT Pruritis - Summary of Differences Within Groups (P-value)

Summary of Differences Within Groups				
Intervals		Control	30CH	200CH
Initial vs First Half	0 mins (baseline) vs 30 mins	0.273	0.024	0.450
Initial vs Second Half	0 mins (baseline) vs 60 mins	0.026	0.016	0.042
First Half vs Second Half	30 mins vs 60 mins	0.014	0.016	0.041

In terms of the significant differences, p-values of 0,05 are indicated in red, and p-values of 0,10 are indicated in blue. These statistics were derived by means of the Wilcoxon

Signed Ranks Test. For the full statistical analysis from which this summary is derived, refer to Appendix G-3.

4.5.5.1 Group A – Control

As illustrated in Figure 4.8, the control group displayed significant and steady improvement of the ENT pruritis symptoms after fifteen minutes, before which an aggravation was reported by one of the participants.

As depicted in Table 4.26, the p-value is greater than 0,05 and 0,10 at the initial versus first-half interval, indicating minimal statistical change during that period. The p-value at the other two intervals however, is less than 0,05 indicating a substantial statistical change in the second half of the study.

4.5.5.2 Group B – *Sabadilla officinarum 30CH*

As illustrated in Figure 4.8, the group receiving *Sabadilla officinarum 30CH* displayed a significant and steady improvement of the ENT pruritis symptoms until forty-five minutes, where after there was only a slight improvement.

As depicted in Table 4.26, the p-value is less that 0,05 at all intervals over the course of the hour, indicating a significant statistical improvement.

4.5.5.3 Group C – *Sabadilla officinarum 200CH*

As illustrated in Figure 4.8, the group receiving *Sabadilla officinarum 200CH* displayed very little change until thirty minutes, after which it steadily improved to fifty-seven percent at sixty minutes.

As depicted in Table 4.26, the p-value is greater than 0,05 and 0,10 at the initial versus fist-half interval, indicating little statistical improvement in the first half of the study.

However, the p-value is less than 0,05 at the other two intervals, indicating significant statistical change over the last half hour.

4.5.5.4 Comparative Group Results of ENT Pruritis

All three groups showed a considerable improvement.

However, after both the experimental groups showed a more rapid onset of action at fifteen minutes, the group which received *Sabadilla officinarum 200CH* showed insignificant improvement, whilst the group which received *Sabadilla officinarum 30CH* and the control group steadily improved.

Overall, *Sabadilla officinarum 30CH* displayed a marginally better response throughout the hour, but at the conclusion of the study, both this group, and the control group scored identically with sixty-two percent improvement of the ENT pruritis symptoms.

4.6 Data Obtained from Response to Treatment Questionnaire

Patients were required to complete a response to treatment questionnaire (Appendix E) on the completion of their hour-long study. This data was obtained for the purpose of descriptive statistics, to determine whether:

- Participants had taken any other medication on the day of the study.
- Participants felt that their treatment was effective or not.
- Participants' specific symptoms had changed status.

4.6.1 Use of Other Medication on the Day of the Study

Of the twenty-nine participants who completed this section of the questionnaire, one hundred percent reported not having taken any other medication on the day of the study, as depicted in Table 4.27.

Table 4.27 Illustrates the Use of Other Medication on the Day of the Study

	Did you take any other hay fever medication on the day of the study	
	Count	Percent
No	29	100.0%
Total	29	100.0%

4.6.2 Control Group

Table 4.28 Status of Individual Symptoms At the Conclusion of the Study – Control Group

Symptom		N/A	Improvement	Constant	Aggravation	Total
Rhinorrhoea	Count		2	8		10
	Percent		20.0%	80.0%		100.0%
Nasal Congestion	Count	5	3	2		10
	Percent	50.0%	30.0%	20.0%		100.0%
Sneezing	Count		5	5		10
	Percent		50.0%	50.0%		100.0%
Ocular Symptom: Eyes Itchy	Count	3	1	6		10
	Percent	30.0%	10.0%	60.0%		100.0%
Ocular Symptom: Eyes Watery	Count	5	2	3		10
	Percent	50.0%	20.0%	30.0%		100.0%
Ocular Symptom Eyes Red	Count	4	2	4		10
	Percent	40.0%	20.0%	40.0%		100.0%
Pruritis Symptom: Itchy Nose	Count	5	2	3		10
	Percent	50.0%	20.0%	30.0%		100.0%
Pruritis Symptom: Itchy Palate	Count	6	1	2	1	10
	Percent	60.0%	10.0%	20.0%	10.0%	100.0%
Pruritis Symptom: Itchy Throat	Count	8	2			10
	Percent	80.0%	20.0%			100.0%
Pruritis Symptom: Itchy Ears	Count	10				10
	Percent	100.0%				100.0%
Mental symptoms	Count	5	2	3		10
	Percent	50.0%	20.0%	30.0%		100.0%
Sleep problems	Count	9		1		10
	Percent	90.0%		10.0%		100.0%
Self-esteem	Count	7	1	2		10
	Percent	70.0%	10.0%	20.0%		100.0%

As reflected in Table 4.28, participants were further required to report on whether their symptoms had improved, remained constant, or aggravated by the end of the hour-long study. Symptoms not experienced were marked as non-applicable.

A vast majority of the participants in the control group reported that their symptoms had remained constant. Only one participant reported an aggravation of palatal pruritis experienced.

Table 4.29 Overall Relief of Symptoms – Control Group

	Control	
	Overall relief of symptoms	
	Count	Percent
Yes	5	50.0%
No	5	50.0%
Total	10	100.0%

All ten participants in the control group reported on their overall relief of symptoms after the hour-long study, of which only fifty percent reported overall relief, as depicted in Table 4.29.

4.6.3 *Sabadilla officinarum 30CH*

Table 4.30 Status of Individual Symptoms At the Conclusion of the Study – *Sabadilla officinarum 30CH*

Symptom		N/A	Improvement	Constant	Total
Rhinorrhoea	Count	1	9		10
	Percent	10.0%	90.0%		100.0%
Nasal Congestion	Count	3	6		9
	Percent	33.3%	66.7%		100.0%
Sneezing	Count	2	6		8
	Percent	25.0%	75.0%		100.0%
Ocular Symptom: Eyes Itchy	Count	3	5	1	9
	Percent	33.3%	55.6%	11.1%	100.0%
Ocular Symptom: Eyes Watery	Count	5	4		9
	Percent	55.6%	44.4%		100.0%
Ocular Symptom Eyes Red	Count	2	6		8
	Percent	25.0%	75.0%		100.0%
Pruritis Symptom: Itchy Nose	Count	2	6	1	9
	Percent	22.2%	66.7%	11.1%	100.0%
Pruritis Symptom: Itchy Palate	Count	7	1	1	9
	Percent	77.8%	11.1%	11.1%	100.0%
Pruritis Symptom: Itchy Throat	Count	7		2	9
	Percent	77.8%		22.2%	100.0%
Pruritis Symptom: Itchy Ears	Count	8	1		9
	Percent	88.9%	11.1%		100.0%
Mental symptoms	Count	4	4		8
	Percent	50.0%	50.0%		100.0%
Sleep problems	Count	6	1	2	9
	Percent	66.7%	11.1%	22.2%	100.0%
Self-esteem	Count	5	1	3	9
	Percent	55.6%	11.1%	33.3%	100.0%

As reflected in Table 4.30, participants were further required to report on whether their symptoms had improved, remained constant, or aggravated by the end of the hour-long study. Symptoms not experienced were marked as non-applicable.

A resounding eighty-four percent of the participants in the *Sabadilla officinarum 30CH* group reported that their symptoms had improved.

Table 4.31 Overall Relief of Symptoms – *Sabadilla officinarum 30CH*

30 CH		
	Overall relief of symptoms	
	Count	**Percent**
Yes	8	80.0%
No	2	20.0%
Total	10	100.0%

All ten participants in the *Sabadilla officinarum 30CH* group reported on their overall relief of symptoms after the hour-long study, of which eighty percent reported overall relief, as depicted in Table 4.31.

4.6.4 *Sabadilla officinarum 200CH*

Table 4.32 Status of Individual Symptoms At the Conclusion of the Study – *Sabadilla officinarum 200CH*

Symptom		N/A	Improvement	Constant	Total
Rhinorrhoea	Count		8	2	10
	Percent		80.0%	20.0%	100.0%
Nasal Congestion	Count	2	4	4	10
	Percent	20.0%	40.0%	40.0%	100.0%
Sneezing	Count		9	1	10
	Percent		90.0%	10.0%	100.0%
Ocular Symptom: Eyes Itchy	Count	3	3	3	9
	Percent	33.3%	33.3%	33.3%	100.0%
Ocular Symptom: Eyes Watery	Count	3	5	1	9
	Percent	33.3%	55.6%	11.1%	100.0%
Ocular Symptom Eyes Red	Count	3	3	3	9
	Percent	33.3%	33.3%	33.3%	100.0%
Pruritis Symptom: Itchy Nose	Count	5	4	1	10
	Percent	50.0%	40.0%	10.0%	100.0%
Pruritis Symptom: Itchy Palate	Count	5	2	3	10
	Percent	50.0%	20.0%	30.0%	100.0%
Pruritis Symptom: Itchy Throat	Count	7	1	2	10
	Percent	70.0%	10.0%	20.0%	100.0%
Pruritis Symptom: Itchy Ears	Count	8	2		10
	Percent	80.0%	20.0%		100.0%
Mental symptoms	Count	8	1	1	10
	Percent	80.0%	10.0%	10.0%	100.0%
Sleep problems	Count	7	1	1	9
	Percent	77.8%	11.1%	11.1%	100.0%
Self-esteem	Count	8		2	10
	Percent	80.0%		20.0%	100.0%

As reflected in Table 4.32, participants were further required to report on whether their symptoms had improved, remained constant, or aggravated by the end of the hour-long study. Symptoms not experienced were marked as non-applicable.

A sixty-four percent of the participants in the *Sabadilla officinarum 200CH* group reported that their symptoms had improved.

Table 4.33 Overall Relief of Symptoms – *Sabadilla officinarum 200CH*

200CH		
	Overall relief of symptoms	
	Count	**Percent**
Yes	7	87.5%
No	1	12.5%
Total	8	100.0%

Eight of the ten participants in the *Sabadilla officinarum 200CH* group reported on their overall relief of symptoms after the hour-long study, of which eighty-eight percent reported overall relief, as depicted in Table 4.33.

CHAPTER FIVE

DISCUSSION

Allergic rhinitis is a common allergic reaction affecting the nose, eyes, throat, and respiratory system. Despite the advances and development of drugs, it continues to flourish worldwide, with an alarming increase in incidence, especially over the last fifty years (Frase and Weiser, 1995 and Levy, 2000). This disease also has a marked debilitating effect on the overall health of the sufferer, often resulting in mental symptoms and limiting the social interactions of the individual (Thornhill and Kelly, 2000). Conventional treatments result in many dangerous adverse effects (Weldon, 1998). Finding alternative ways of treating and managing allergic rhinitis is becoming vital. Homoeopathically prepared *Sabadilla officinarum 30CH* and *Sabadilla officinarum 200CH* provide a gentle, yet valuable alternative to conventional treatments.

5.1 Questionnaires and Diary Cards

Questionnaires were completed to establish whether participants had allergic rhinitis (prediagnosed or other), to assess whether participants were eligible for the study, and to derive descriptive statistics. The diary cards were similarly used to assess the severity of the allergic rhinitis, and its impact on the daily activities of the participants.

5.2 Factors Contributing to Results

When interpreting the results many factors have to be taken into consideration, as they may impact on the findings, and can thus be considered as exogenous factors and internal variables.

5.2.1 Statistical Factors

Tests for allergic rhinitis tend to be extremely subjective, and no validated assessment is presently available that can be employed in population studies thereof (Annesi-Maesano *et al*, 2002). Furthermore, larger sample groups would better reflect the results, as they allow for more flexibility of the statistics.

5.2.2 Patient Compliance

As this study was conducted outside of the clinical setting, it is difficult to assess patient compliance. There is no means to gauge whether allergen exposure remained constant or not. There is the risk that patients did not fill their reports in honestly and accurately. The study may not have been perfectly time controlled as participants may have recorded their results outside the specified times. It is also possible that participants may indeed have taken medicine on the day and not reported it, or there may have been smokers too embarrassed to admit it to a healthcare professional.

5.2.3 Patient Subjectivity

Unfortunately all assessments for allergic rhinitis symptoms are subjective, that is why it was so important to establish whether there were any differences in the baseline values at the start and throughout the duration of the study (See Appendix G-1). It is also difficult to avoid open-ended questions. As all participants reflect individuality, there would naturally be a discrepancy between what participants considered the severity of a symptom to be or what they considered to be a significant improvement thereof.

Furthermore, many patients were sceptical as to the efficacy of homoeopathy to begin with, and this may have had a negative impact on the results. Many patients were also convinced from the outset, that they were getting the placebo, despite my assurances that their medication may well be medicated.

5.2.4 Self-limiting Effect of Allergic Rhinitis Attack

The majority of relevant literature states that an allergic rhinitis attack typically lasts an hour or longer (Mackay and Durham, 1997), but is not specific as to the exact average duration thereof.

An interesting trend emerged from the study, as is evident in Figure 4.4 – Figure 4.8. Regardless of the performances of the three groups in the initial stages of the study, be they significant or extremely poor, bizarrely all groups showed a substantial improvement after forty-five minutes. This finding may well suggest that allergic rhinitis attacks are self-limiting, and last less than an hour, which would explain why all groups showed this improvement after forty-five minutes.

5.3 General Findings

As illustrated in Table 4.2 both sexes were represented by fifty percent. This finding validates the recorded incidence of allergic rhinitis being equally distributed between the sexes (Ricketti, 1997).

Table 4.2 illustrates that the mean age of participants was thirty years. This is consistent with the relevant literature, which states that allergic rhinitis symptoms begin in childhood or adolescence, remain severe until middle age at which time they improve, and only ameliorate in old age (Mygind *et al.*, 1997).

A possible oversight in this study was the failure to record social class, ethnicity, seasonal or perennial onset, genetic predisposition, and miasmatic disposition, as these factors were discussed, if briefly, in the literature review.

All the patients reported that they suffer from hay fever, although only fifty-six percent had previously been diagnosed by a professional medical practitioner, as illustrated in Table 4.4. This in itself is not of much consequence, as all the participants presented

with a symptom picture typical of that of allergic rhinitis, and thus all passed the inclusion criteria for this study.

As depicted in Table 4.3, the majority of the participants (eighty-three percent) reported that they typically suffer from all five hay fever symptoms studied in this research, with the vast majority of participants reporting moderate to very severe symptoms. The literature states that most patients may only present with two or more symptoms (Mackay and Durham, 1997), but this study reflects that they typically suffer from at least four of the five symptoms discussed.

Open-ended questions on the eligibility questionnaires (Appendix A) and on the response to treatment questionnaires (Appendix E) allowed the participants to comment on the exact presentation of their symptoms, and the summarised findings were:

- The rhinorrhoea experienced is typically bland and watery, and alternated with nasal congestion. This finding is consistent with the literature, as a purulent discharge is not seen in uncomplicated allergic rhinitis (Vogt, 1990 and Norris, 1995).
- The majority of the participants reported suffering from nasal congestion and sinusitis, and it is known that chronic sinusitis often co-exists with allergic rhinitis (Zoorob and Morelli, 2002).
- Twenty-eight of the thirty participants reported that sneezing was a severe symptom, and this is not a suprising finding, as it is considered to be the most characteristic symptom of allergic rhinitis (Vogt, 1990).
- The ocular symptoms of pruritis, tearing, and redness were reported by the participants, and is consistent with the literature (Ricketti, 1997).
- ENT pruritis was reported, especially of the nose and throat, with some of the participants suffering from palatal pruritis, but very few reports of itchy ears. This substantiates the literature reports (Thornhill and Kelly, 2000).

In terms of hay fever related symptoms, the following results were derived from Table 4.5.

More than seventy-three percent of the participants reported hay fever symptoms lasting longer than an hour, validating the literature which states that patients usually present with symptoms occurring for more than an hour on the days of an allergic attack (Mackay and Durham, 1997).

However, despite the literature report that patients have paroxysms of ten to twenty sneezes in a row (Ricketti, 1997), the finding for this symptom is less conclusive, as only forty-five percent of participants reported suffering from as many consecutive sneezes.

Sixty-six percent of the participants reported mental symptoms such as irritability and moodiness related to hay fever, consistent with findings of hay fever related mental symptoms also including malaise and listlessness (Norris, 1995).

Another typical mental symptom related to allergic rhinitis is sleepiness during the day and trouble sleeping at night (Rapp and Frankland, 1976). Only forty-six percent of the participants reported problems related to sleep as a result of a hay fever attack, commenting that the problem was sleepiness during the day. This finding is inconclusive, as only a slightly larger percentage of fifty-four percent reported no sleep related problems due to hay fever.

Despite patient reports of overall poorer self-image (Weldon, 1998), the majority of participants in this study did not experience this hay fever related symptom, with only twenty-one percent reporting that they do. However, interestingly, several participants did report that they suffer from lower self-esteem, especially due to the redness and swelling of their noses and eyes.

Sixty-seven percent of the participants reported suffering from other allergies such as asthma, and known allergic susceptibility to irritants such as animal dander and grasses. This is not a suprising finding, as a personal history of co-existing allergies such as asthma, urticaria, and eczematous dermatitis are common (Thornhill and Kelly, 2000).

Non-specific irritants such as tobacco smoke are considered to be causative factor of allergic rhinitis (Kay, 1997). However, as illustrated in Table 4.9, the results of this study are inconclusive as to determining whether smoking cigarettes is a major aetiology of allergic rhinitis, as the majority of participants were non-smokers.

As depicted in Table 4.27, none of the participants reported having taken other allergic rhinitis medication or aspirin on the day of the study. This is an important factor concerning the results of this study, as the extraneous variables and outside interference of drug-interactions, and multiple medications and their contribution to relief can be disregarded as having played a role in the outcome of this study.

A study on a larger sample group may well better represent the statistical trends, and whilst these trends are in themselves helpful, it is of utmost importance never to lose sight of the fact that the patient is not merely a diagnostic entity or simply a statistical tool. Homoeopathy epitomises holistic healing as it seeks to treat the individual. Even if only a small percentage of patients suffer from a specific symptom, the symptom is of no less importance. On the contrary, in homoeopathic treatment it is these rare, strange or peculiar symptoms which are often the most important (Vithoulkas, 1985).

5.4 Control (Placebo) Group

Ten participants formed the control group and received unmedicated powders (placebo).

Table 4.28 indicates that sixty-one percent of the participants in this group reported that their symptoms remained constant over the hour of the study. Futhermore, only fifty percent of this group reported overall relief from symptoms as depicted in Table 4.29. This offers evidence that the placebo did not play a significant role in this study.

5.4.1 Rhinorrhoea

The thirty-eight percent improvement is not significant, as reflected in Figure 4.4, and it is to be considered consistent with the placebo effect demonstrated in anti-histamine studies, which can be quite high (Potter *et al.*, 2001).

5.4.2 Nasal Congestion

As indicated in Figure 4.5, there was a negligible improvement of less than ten percent in the initial stages of the study, which slowly increased to thirty-eight percent by sixty minutes.

5.4.3 Sneezing

As indicated in Figure 4.6, there was a marked improvement by the end of the hour, but it did not have the rapid onset of action seen in the two experimental groups, nor was it as effective as either of the experimental groups.

5.4.4 Ocular Symptoms

As indicated in Figure 4.7, there was a significant improvement of sixty-eight percent at the end of the hour, but onset of action was more gradual than either of the experimental groups at thirty minutes.

5.4.5 Pruritis of ENT

As indicated in Figure 4.8, there was a significant improvement of sixty percent at the end of the hour, but onset of action was more gradual than the experimental group which received *Sabadilla officinarum 30CH*. Furthermore one participant in this group reported an aggravation at fifteen minutes.

5.5 Experimental Group One – *Sabadilla Officinarum 30CH*

There were ten participants in the first experimental group. Participants in this group received powders medicated with *Sabadilla officinarum 30CH.*

Table 4.30 indicates that a resounding eighty-four percent of the participants in this group reported that their symptoms improved over the hour of the study. In addition, eighty percent of this group reported overall relief from symptoms as depicted in Table 4.31. This offers evidence that *Sabadilla officinarum 30CH* is highly effective in the treatment of hay fever symptoms.

It is not suprising that *Sabadilla officinarum* is more effective in the lower potency, as it is an accepted homoeopathic truth, that low potencies show more affinity for physical complaints, whereas higher potencies are more effective for treating mental symptoms. This verifies the findings in the literature report, which states that the advocated dose is the third to the thirtieth potency (Varna and Vaid, 1997).

5.5.1 Rhinorrhoea

As indicated in Figure 4.4, this potency displayed a rapid onset of action until thirty minutes, and no significant improvement thereafter. On this evidence more frequent dosing with the same potency should be considered.

5.5.2 Nasal Congestion

As indicated in Figure 4.5, there was substantial improvement with this potency. The onset of action at this potency was significantly higher than that of the other two groups, with a twenty-five percent improvement between fifteen and thirty minutes, after which its action was more moderate. On this evidence more frequent dosing with the same potency should be considered.

5.5.3 Sneezing

As indicated in Figure 4.6, the most marked improvement of symptom severity is evident for sneezing. At this potency there was a rapid onset of action, and approximately an eighty-eight percent improvement overall, verifying that *Sabadilla officinarum 30CH* is well indicated for sneezing, verifying the literature which states that the primary symptom arising from *Sabadilla officinarum* is sneezing (Allan, 2000). This validates the law of similars employed in homoeopathy.

5.5.4 Ocular Symptoms

As indicated in Figure 4.7, there was a rapid onset of action, and a significant improvement of seventy-two percent at the end of the hour. On this evidence more frequent dosing with the same potency should be considered, perhaps forty-five minutes after the first dose, at which time its improvement is less marked.

5.5.5 Pruritis of ENT

As indicated in Figure 4.8, there was a significant improvement for the first forty-five minutes, and little improvement thereafter, with sixty percent of the symptom severity reduced on the hour. More frequent dosing with the same potency should be considered at forty-five minutes.

5.6 Experimental Group Two – *Sabadilla Officinarum 200CH*

There were ten participants in the second experimental group. Participants in this group received powders medicated with *Sabadilla officinarum 200CH.*

Table 4.32 indicates that sixty-four percent of the participants in this group reported that their symptoms improved over the hour of the study. In addition, eighty-eight percent of this group reported overall relief from symptoms as depicted in Table 4.33. This offers evidence that *Sabadilla officinarum 200CH* is highly effective in the treatment of hay fever symptoms.

Whilst *Sabadilla officinarum 200CH* proved to be effective, higher potencies are generally regarded to be more effective in the treatment of mental symptoms, and acute exacerbations of disease. However, as acute as the symptoms of hay fever may seem, it must be remembered that they are part of a complex chronic disease picture, with almost all of the participants having suffered from allergic rhinitis since childhood or adolescence.

5.6.1 Rhinorrhoea

As indicated in Figure 4.4, this potency displayed the most substantial improvement, with a relatively rapid onset of action, and is well indicated for rhinorrhoea related to hay fever.

5.6.2 Nasal Congestion

As indicated in Figure 4.5, this potency displayed little affinity for nasal congestion related to hay fever. There also appeared to be an aggravation at forty minutes, however this is followed by a twenty-five percent improvement in the last fifteen minutes.

Whilst improvement in symptoms is generally regarded as a positive outcome, by no means does that imply, homoeopathically, that an aggravation is a negative outcome. In some cases patients may experience an homoeopathic aggravation after taking an homoeopathic remedy. This phenomenon is usually noted in sensitive patients with an allergic disposition. Hahnemann states that medication must be stronger than the ailment in order to cure it, and considered an aggravation to be a good prognosis that disease will yield to the first dose (Hanemann, 1998).

However in the instance of an aggravation after the first dose, sensitivity due to allergic predisposition must be considered, as in the single patient whose itchy palate aggravated (See Table 4.17), or the general aggravation observed in this potency (see Figure 4.5). If the aggravation is severe, an antidote to the remedy may be administered, or alternately the same remedy may be administered in a lower dose to antidote the effects of the remedy administered. Remedies known to antidote the effects of *Sabadilla officinarum* include: *Camphora, Conium maculatum, Pulsatilla pratensis, Lachesis muta*, and *Lycopodium clavatum* (Vermeulen, 1997).

5.6.3 Sneezing

As indicated in Figure 4.6, the most marked improvement of symptom severity is evident for sneezing. This potency displayed the most rapid onset of action, and approximately an eighty-five percent improvement overall, verifying that *Sabadilla officinarum 200CH* is well indicated for sneezing.

5.6.4 Ocular Symptoms

As indicated in Figure 4.7, there was a rapid onset of action, and a significant improvement of sixty-eight percent at the end of the hour. On this evidence more frequent dosing with the same potency should be considered, perhaps thirty five minutes after the first dose, at which time its improvement is moderately less marked.

5.6.5 Pruritis of ENT

As indicated in Figure 4.8, there was little improvement for the first thirty minutes, and marked improvement thereafter, with sixty percent of the symptom severity reduced on the hour.

5.7 Homoeopathy

This study has proved that the homoeopathic remedy *Sabadilla officinarum*, prepared in potencies of 30CH and 200CH is effective in the treatment of allergic rhinitis.

Homoeopathic medicines are usually administered internally, as it is believed that all diseases, even externalized diseases, originate from an internal disturbance, and are cured by the internal administration of the correct remedy (Sankaran, 1996).

The vital force refers to the body's natural defence mechanism (immune system). Any disturbance of this vital energy results in the disturbance of the whole human economy, and shows itself through outward manifestations such as symptoms (Roberts, 2000).

Homoeopathic medicines stimulate the body's vital force to establish the body's best possible reaction to the interference, and to re-establish the equilibrium of the immune system (Vithoulkas, 1980).

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

This study has proved that homoeopathically prepared *Sabadilla officinarum 30CH* and *Sabadilla officinarum 200CH* definitely have a positive inhibitory effect in the treatment of allergic rhinitis. There was a marked decrease or complete resolution of symptoms experienced by the patients, who themselves reported the effectiveness of their treatments.

None of the participants in either of the two medicated groups reported any adverse effects during the treatment period. This study has clearly established that *Sabadilla officinarum,* homoeopathically prepared in potencies of 30CH and 200CH, is a gentle, safe, and effective treatment for allergic rhinitis, and can therefore be recommended without reservation for the treatment of allergic rhinitis, as a safe alternative to harmful allopathic drugs.

6.2 Recommendations

This study proved *Sabadilla officinarum,* homoeopathically prepared in potencies of 30CH and 200CH has a positive effect in the treatment of allergic rhinitis. At the end of this study, the following recommendations have to be made:

- Further studies should be conducted to verify whether the findings of this study are conclusive, employing *Sabadilla officinarum* prepared in the same potencies, and in other potencies, specifically lower potencies. It is also worth considering a study of allergic rhinitis employing other homoeopathic remedies such as *Galphimia glauco*, Lung histamine, and *Luffa operculata,* or using the miasmatic remedy *Psorinum.*

- It would be beneficial to test the efficacy of homoeopathic remedies when the dose frequently is increased.

- It would be worthwhile conducting research into a homoeopathic remedy versus a conventional anti-allergy drug and placebo.

- Research should be conducted on larger sample groups which will reflect more accurate statistical evaluation.

- Many potential participants did not take part in the study because of the minimum age requirement of eighteen years. Children should be included in allergic rhinitis studies, as the related literature states that the incident of onset of allergic rhinitis is greatest in adolescence, with symptoms typically remaining constant until middle age at which time they improve (Mygind *et al*, 1997 and Weldon 1998).

- It may be advisable to conduct supervised clinical trials, as to better control patient compliance. I struggled to recruit sufficient participants who saw the study through to completion, and returned their results within the time constraints. I was forced to disband my first recruitment of participants when the dropouts exceeded more than two participants in a group, and became too high to be statistically viable. Being a double-blind study, and having only ordered sufficient medication for the thirty participants required, I saw no other scientific solution. For my second recruitment, I ordered more medication then necessary for each group, and recruited more participants than I required in order to complete the study. Fortunately this approach worked, for while the dropouts still occurred, I was able to simply exclude them from the study without having to compromise numbers of participants within the groups.

- It may be advisable to recruit participants before the beginning of the hay fever season, and prediagnose allergic rhinitis by means of skin-prick tests.

- Tests for allergic rhinitis tend to be very subjective as no validated assessment of allergic rhinitis is presently available that can be employed in population studies in the absence of objective measurements of allergy and medical diagnosis. I based my study on the only scientifically accepted model that I could find at the time, the model used in the Telfast study (Potter and Schoeman, 2001). However, I discovered a new quantitative *a priori* proposed Score For Allergic Rhinitis (SFAR) ranging between 0 and 16, which has been developed by experts in France (Annesi-Maesano *et al.*, 2002), which may prove to be a better model for assessing allergic rhinitis (See Appendix H).

- A wash-out period during which placebo is administered is suggested to exclude the carry-over effect of conventional medicine. This should be approximately a week, except for long-term acting anti-histamines and corticosteroids (Frew *et al.*, 1991).

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APPENDIX A: ELIGIBILITY QUESTIONNAIRE

Date: _____

Surname: _____ First Names: _____

Tel: (h)_____ (w)_____ (c)_____

Date of birth: _____ Age: _____ Sex: _____

Do you suffer from hay fever? (Circle) Yes No
Have you previously been diagnosed as having hay fever? (Circle) Yes No
At what age did your hay fever symptoms start? _____ years of age

Kindly score the symptoms you usually experience when suffering from a hay fever attack, in the table below, using the severity of symptom scores (0-4).

Severity of Symptoms Scores

- 0 = Absent
- 1 = Mild - symptom is present, but not troublesome or annoying
- 2 = Moderate - symptom is troublesome, but does not interfere with normal activity or sleep
- 3 = Severe - symptom is troublesome enough to interfere with normal activity and / or sleep
- 4 = Very severe - symptom is severe enough to warrant medication

Symptoms	Score	Comments (colour, frequency, etc…)
Rhinorrhoea (Watery/ Runny Nose)		
Nose (Congested/ Blocked/ Stuffy)		
Sneezing		
Eyes (Itchy and/ or Watery and/ or Red)		
Itchy Nose and/ or Palate and/ or Throat and/ or Ears		
TOTAL		

Do you experience any of the following symptoms during an hay fever attack? (Please circle the appropriate answer).

- Hay fever symptoms that typically last longer than an hour? Yes No
- More than ten sneezes in a row Yes No
- Mental symptoms (irritability, difficult concentration, etc...)? Yes No

Kindly list and comment: 1. _____

2. _____

- Problems related to sleep (sleepiness or insomnia)? Yes No

Kindly list and comment: 1. _____

2. _____

- Lower self-esteem as a result of your hay fever? Yes No

Kindly list and comment: 1. _____

2. _____

Kindly list any other symptoms you experience during a hay fever attack (headache, mouth breathing, loss of taste, etc...): 1. _____

2. _____

Kindly list any medication you currently use for hay fever and comment on how effective it is for you:

1. _____

2. _____

Do you suffer from any allergies, asthma, respiratory disorders or sinusitis? Yes No

Please list and comment: 1. _____

2. _____

Do you smoke? Yes No

APPENDIX B: INFORMATION AND CONSENT FORM

The effect of *Sabadilla officinarum* in the treatment of allergic rhinitis

Dear Participant,

Allergic rhinitis, otherwise known as hay fever, continues to flourish worldwide despite the advances and development of drugs and other treatments. The problem of hay fever is still a great concern, as it is impossible to remove the cause thereof from the environment. The purpose of this study is to determine the effect of homeopathic remedy, *Sabadilla officinarum*, as a treatment for the relief of allergic rhinitis (hay fever).

You have been selected to participate in this study. You will be randomly placed into one of three groups of ten, consisting of a control group and two experimental groups. Neither the researcher, nor the participants will be informed as to which group they are assigned. The control group will receive a placebo, and the experimental groups will receive the medication, namely *Sabadilla officinarum 30CH or Sabadilla officinarum 200CH.*

You will be required to take home with you: a single dose of the treatment, a diary card, and a "Response to Treatment" questionnaire. At the time of a hay fever attack, immediately before taking your medication, you are to score your symptoms in the 0 minutes column, on your diary card, using the severity of symptom scores (0-4). You are then to take the medication orally, by dissolving it under your tongue. Once you have taken your medication, you are to score your symptoms at fifteen minute intervals for the next hour, in the columns for 15, 30, 45 and 60 minutes respectively. You are kindly requested to take no other hay fever medication prior to or during the hour of the study. You are requested to return the diary card and questionnaire to me on their completion.

The potential benefits for those participating in the study are that the homeopathic treatments may reduce or completely relieve your hay fever suffering. Irrespective of the treatment assigned, all participants will contribute to medical knowledge, resulting in the greater efficacy to the therapeutic management of people who suffer from hay fever. Participation in this study is voluntary and you are free to refuse to participate or to withdraw your consent and to discontinue participation at any time. Such refusal or discontinuance will not affect your regular treatments or medical care in any way. A signed copy of this consent form will be made available to you.

I have fully explained the procedures, identifying those, which are investigational, and have explained their purpose. I have asked whether any questions have arisen regarding the procedures and have answered these questions to the best of my ability. If you should have any queries during the trial, please contact me on 082 898 7743.

Date: _____ Miles Danks B.TechHom Signature: _____

I have been fully informed of the procedures to be followed, including those, which are investigational and have been given a description of the attendant discomforts, risks, and benefits to be expected and the appropriate alternative procedures. In signing this consent form I agree to this method of treatment and I understand that I am free to withdraw my consent and discontinue my participation in this study at any time. I understand that if I have any questions at any time, they will be answered.

Date:_____Patient:_____Signature:_____

APPENDIX C: CONFIDENTIAL PATIENT INFORMATION

File Number: _____ Pulv no:_____

Date: _____

Surname: _____

First name/s: _____

Tel: (h)_____ (w)_____ (c)_____

Date of birth: _____ Age: _____ Sex: _____

Kindly list any chronic medication or other medication you take frequently, and state the reason therefore:

1. _____

2. _____

3. _____

4. _____

5. _____

APPENDIX D: DIARY CARD

Date: _____ File Number: _____ Pulv Number:_____

Surname: _____

First Name/s: _____

Date of birth: _____ Age: _____ Sex: _____

At the time of an hay fever attack, **immediately before taking your medication**, you are to **score your symptoms in the 0 minutes column,** in the table below, using the severity of symptoms scores (0 to 4).

Severity of Symptoms Scores

- 0 = Absent
- 1 = Mild - symptom is present, but not troublesome or annoying
- 2 = Moderate - symptom is troublesome, but does not interfere with normal activity or sleep
- 3 = Severe - symptom is troublesome enough to interfere with normal activity and / or sleep
- 4 = Very severe - symptom is severe enough to warrant medication

Once you have taken your medication, you are to **score your symptoms at fifteen minute intervals for the next hour, in the columns for 15, 30, 45 and 60 minutes respectively**. You are kindly requested to **take no other hay fever medication prior to or during the hour of the study**

	TIME				
	0 minutes	**15 minutes**	**30 minutes**	**45 minutes**	**60 minutes**
Rhinorrhoea (Watery/ Runny Nose)					
Nose (Congested/ Blocked/ Stuffy)					
Sneezing					
Eyes (Itchy and/or Watery and/ or Red)					
Itchy Nose and/ or Palate and/ or Throat and/ or Ears					

APPENDIX E: RESPONSE TO TREATMENT QUESTINNAIRE

Did you experience overall relief of symptoms? (Circle) Yes No

If so, what percentage improvement did you experience? (Circle)

10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

Please indicate whether the severity of your symptoms improved (Circle 'Improvement'), remained the same (Circle 'Constant) or got worse (Circle 'Aggravation') **at the end of the hour- long treatment**. If you did not experience a particular symptom, kindly circle 'N/A'.

- **Rhinorrhoea (Watery/ Runny Nose)** N/A Improvement Constant Aggravation

Kindly comment: _____

- **Nose (Congested/ Blocked/ Stuffy)** N/A Improvement Constant Aggravation

Kindly comment: _____

- **Sneezing** N/A Improvement Constant Aggravation

Kindly comment: _____

- **Eyes:**

  Itchy N/A Improvement Constant Aggravation

  Watery N/A Improvement Constant Aggravation

  Red N/A Improvement Constant Aggravation

Kindly comment: _____

_____

- **Itchy Nose** N/A Improvement Constant Aggravation

Kindly comment: _____

- **Itchy Palate** N/A Improvement Constant Aggravation

Kindly comment: _____

- **Itchy Throat** N/A Improvement Constant Aggravation

Kindly comment: _____

- **Itchy Ears** N/A Improvement Constant Aggravation

Kindly comment: _____

- **Mental symptoms (irritability, etc...)** N/A Improvement Constant Aggravation

Kindly comment: _____

- **Sleep problems (sleepiness, etc...)** N/A Improvement Constant Aggravation

Kindly comment: _____

- **Self-esteem** N/A Improvement Constant Aggravation

Kindly comment: _____

Kindly list any other symptoms or new symptoms you experienced during or after the hour of treatment:

1. _____

2. _____

3. _____

4. _____

5. _____

Did you take any other hay fever medication or aspirin on the day of the study (Circle) Yes No

If so, please list such medication:

1. _____

2. _____

3. _____

I would like to take this opportunity to thank you for your participation in this study, and the valuable contribution you have made to my Masters degree in Homeopathy, and hopefully, the successful management of the of hay fever at large.

Many thanks,

_____
Miles Danks

APPENDIX F: MATERIALS USED

30 x Unmedicated Powders	Natura
30 x Powders medicated with Sabadilla officinarum 30CH	Natura
30 x Powders medicated with Sabadilla officinarum 200CH	Natura

APPENDIX G-1: KRUSKAL-WALLIS TEST

Summary

P-values Between Groups:			
	Initial	**First Half**	**Second Half**
Rhinorrhoea	0.875	0.206	0.123
Nose	0.216	0.623	0.358
Sneezing	0.193	**0.052**	0.144
Eyes	0.515	0.832	0.986
Itchiness	0.347	0.664	0.694

P-values Between Groups with Differences:			
	First Difference	**Second Difference**	**Third Difference**
Rhinorrhoea	**0.027**	0.209	0.388
Nose	0.163	0.124	0.317
Sneezing	0.493	0.436	0.251
Eyes	0.219	0.357	0.730
Itchiness	0.223	0.266	0.486

Key:	**First Difference = Initial minus First Half**
	Second Difference = Initial minus Second Half
	Third Difference = First Half minus Second Half

Initial

Descriptives

		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
						Lower Bound	Upper Bound		
Rhinorrhoea_0	Control	10	2.80	1.317	.416	1.86	3.74	0	4
	30 CH	8	3.00	.926	.327	2.23	3.77	1	4
	200 CH	10	2.80	.919	.291	2.14	3.46	1	4
	Total	28	2.86	1.044	.197	2.45	3.26	0	4
Nose_0	Control	10	1.50	1.509	.477	.42	2.58	0	4
	30 CH	9	2.56	1.130	.377	1.69	3.42	0	4
	200 CH	10	1.70	1.418	.448	.69	2.71	0	4
	Total	29	1.90	1.398	.260	1.36	2.43	0	4
Sneezing_0	Control	10	3.20	.789	.249	2.64	3.76	2	4
	30 CH	8	3.25	1.035	.366	2.38	4.12	1	4
	200 CH	10	2.50	1.080	.342	1.73	3.27	1	4
	Total	28	2.96	.999	.189	2.58	3.35	1	4
Eyes_0	Control	10	2.00	1.333	.422	1.05	2.95	0	4
	30 CH	10	2.60	1.174	.371	1.76	3.44	0	4
	200 CH	10	2.30	1.337	.423	1.34	3.26	0	4
	Total	30	2.30	1.264	.231	1.83	2.77	0	4
Itchiness_0	Control	10	1.70	1.418	.448	.69	2.71	0	4
	30 CH	8	2.38	1.302	.460	1.29	3.46	0	4
	200 CH	10	1.50	1.269	.401	.59	2.41	0	3
	Total	28	1.82	1.335	.252	1.30	2.34	0	4

Ranks			
	Group	**N**	**Mean Rank**
Rhinorrhoea_0	**Control**	10	14.60
	30 CH	8	15.50
	200 CH	10	13.60
	Total	28	
Nose_0	**Control**	10	12.75
	30 CH	9	18.94
	200 CH	10	13.70
	Total	29	
Sneezing_0	**Control**	10	16.00
	30 CH	8	17.06
	200 CH	10	10.95
	Total	28	
Eyes_0	**Control**	10	13.15
	30 CH	10	17.50
	200 CH	10	15.85
	Total	30	
Itchiness_0	**Control**	10	13.60
	30 CH	8	17.94
	200 CH	10	12.65
	Total	28	

Test Statistics(a,b)			
	Chi-Square	**df**	**Asymp. Sig.**
Rhinorrhoea_0	.268	2	.875
Nose_0	3.063	2	.216
Sneezing_0	3.290	2	.193
Eyes_0	1.328	2	.515
Itchiness_0	2.118	2	.347
a Kruskal Wallis Test			
b Grouping Variable: Group			

First Half

Descriptives

		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
						Lower Bound	Upper Bound		
Rhinorrhoea: First Half	Control	10	2.5000	1.13039	.35746	1.6914	3.3086	.00	4.00
	30 CH	8	1.6875	1.09992	.38888	.7679	2.6071	.00	3.50
	200 CH	10	2.1000	.80966	.25604	1.5208	2.6792	.50	3.00
	Total	28	2.1250	1.03302	.19522	1.7244	2.5256	.00	4.00
Nose: First Half	Control	10	1.2000	1.22927	.38873	.3206	2.0794	.00	3.00
	30 CH	9	1.7778	1.17556	.39185	.8742	2.6814	.00	3.50
	200 CH	10	1.5000	1.20185	.38006	.6402	2.3598	.00	3.50
	Total	29	1.4828	1.18384	.21983	1.0324	1.9331	.00	3.50
Sneezing: First Half	Control	10	2.1500	.66875	.21148	1.6716	2.6284	.50	3.00
	30 CH	8	1.4375	1.29387	.45745	.3558	2.5192	.00	3.50
	200 CH	10	1.0000	1.20185	.38006	.1402	1.8598	.00	4.00
	Total	28	1.5357	1.14608	.21659	1.0913	1.9801	.00	4.00
Eyes: First Half	Control	10	1.5000	1.20185	.38006	.6402	2.3598	.00	3.50
	30 CH	10	1.7500	1.06066	.33541	.9912	2.5088	.00	3.50
	200 CH	10	1.6000	1.22020	.38586	.7271	2.4729	.00	4.00
	Total	30	1.6167	1.12712	.20578	1.1958	2.0375	.00	4.00
Itchiness: First Half	Control	10	1.4000	1.04881	.33166	.6497	2.1503	.00	3.00
	30 CH	8	1.8125	1.19336	.42192	.8148	2.8102	.00	3.50
	200 CH	10	1.3500	1.20301	.38042	.4894	2.2106	.00	3.00
	Total	28	1.5000	1.12217	.21207	1.0649	1.9351	.00	3.50

Ranks			
	Group	**N**	**Mean Rank**
Rhinorrhoea: First Half	**Control**	10	17.75
	30 CH	8	10.94
	200 CH	10	14.10
	Total	28	
Nose: First Half	**Control**	10	13.20
	30 CH	9	16.94
	200 CH	10	15.05
	Total	29	
Sneezing: First Half	**Control**	10	19.15
	30 CH	8	13.81
	200 CH	10	10.40
	Total	28	
Eyes: First Half	**Control**	10	14.65
	30 CH	10	16.85
	200 CH	10	15.00
	Total	30	
Itchiness: First Half	**Control**	10	13.65
	30 CH	8	16.69
	200 CH	10	13.60
	Total	28	

Test Statistics(a,b)			
	Chi-Square	**df**	**Asymp. Sig.**
Rhinorrhoea: First Half	3.155	2	.206
Nose: First Half	.947	2	.623
Sneezing: First Half	5.904	2	.052
Eyes: First Half	.368	2	.832
Itchiness: First Half	.818	2	.664
a Kruskal Wallis Test			
b Grouping Variable: Group			

Second Half

Descriptives

		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
						Lower Bound	Upper Bound		
Rhinorrhoea: Second Half	Control	10	1.9000	.87560	.27689	1.2736	2.5264	.00	3.00
	30 CH	8	1.2500	1.33631	.47246	.1328	2.3672	.00	3.50
	200 CH	10	1.1000	.73786	.23333	.5722	1.6278	.00	2.00
	Total	28	1.4286	1.01575	.19196	1.0347	1.8224	.00	3.50
Nose: Second Half	Control	10	.6000	.73786	.23333	.0722	1.1278	.00	2.00
	30 CH	9	1.0000	.96825	.32275	.2557	1.7443	.00	3.00
	200 CH	10	1.1500	.91439	.28916	.4959	1.8041	.00	2.50
	Total	29	.9138	.87698	.16285	.5802	1.2474	.00	3.00
Sneezing: Second Half	Control	10	1.0000	.70711	.22361	.4942	1.5058	.00	2.00
	30 CH	8	.6250	.95431	.33740	-.1728	1.4228	.00	2.50
	200 CH	10	.6000	1.14988	.36362	-.2226	1.4226	.00	3.00
	Total	28	.7500	.93789	.17724	.3863	1.1137	.00	3.00
Eyes: Second Half	Control	10	.8500	.91439	.28916	.1959	1.5041	.00	2.50
	30 CH	10	.9000	1.10050	.34801	.1127	1.6873	.00	3.00
	200 CH	10	.9000	1.26491	.40000	-.0049	1.8049	.00	4.00
	Total	30	.8833	1.06418	.19429	.4860	1.2807	.00	4.00
Itchiness: Second Half	Control	10	.7000	.71492	.22608	.1886	1.2114	.00	2.00
	30 CH	8	1.0625	.94255	.33324	.2745	1.8505	.00	2.00
	200 CH	10	.8000	1.11056	.35119	.0056	1.5944	.00	3.00
	Total	28	.8393	.91341	.17262	.4851	1.1935	.00	3.00

Ranks			
	Group	**N**	**Mean Rank**
Rhinorrhoea: Second Half	**Control**	10	18.70
	30 CH	8	12.38
	200 CH	10	12.00
	Total	28	
Nose: Second Half	**Control**	10	12.20
	30 CH	9	15.44
	200 CH	10	17.40
	Total	29	
Sneezing: Second Half	**Control**	10	18.35
	30 CH	8	12.88
	200 CH	10	11.95
	Total	28	
Eyes: Second Half	**Control**	10	15.85
	30 CH	10	15.40
	200 CH	10	15.25
	Total	30	
Itchiness: Second Half	**Control**	10	13.80
	30 CH	8	16.50
	200 CH	10	13.60
	Total	28	

Test Statistics(a,b)			
	Chi-Square	**df**	**Asymp. Sig.**
Rhinorrhoea: Second Half	4.188	2	.123
Nose: Second Half	2.052	2	.358
Sneezing: Second Half	3.879	2	.144
Eyes: Second Half	.028	2	.986
Itchiness: Second Half	.732	2	.694
a Kruskal Wallis Test			
b Grouping Variable: Group			

First Difference

Descriptives

		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
						Lower Bound	Upper Bound		
Rhinorrhoea_0 - Rhinorrhoea: First Half	Control	10	.3000	.48305	.15275	-.0456	.6456	.00	1.50
	30 CH	8	1.3125	.96130	.33987	.5088	2.1162	.00	3.00
	200 CH	10	.7000	.75277	.23805	.1615	1.2385	-1.00	1.50
	Total	28	.7321	.82195	.15533	.4134	1.0509	-1.00	3.00
Nose_0 - Nose: First Half	Control	10	.3000	.82327	.26034	-.2889	.8889	-1.50	1.50
	30 CH	9	.7778	.87003	.29001	.1090	1.4465	.00	3.00
	200 CH	10	.2000	.48305	.15275	-.1456	.5456	-.50	1.00
	Total	29	.4138	.75674	.14052	.1259	.7016	-1.50	3.00
Sneezing_0 - Sneezing: First Half	Control	10	1.0500	1.16548	.36856	.2163	1.8837	-.50	3.50
	30 CH	8	1.8125	1.41263	.49944	.6315	2.9935	.50	4.00
	200 CH	10	1.5000	1.02740	.32489	.7650	2.2350	.00	3.00
	Total	28	1.4286	1.19190	.22525	.9664	1.8907	-.50	4.00
Eyes_0 - Eyes: First Half	Control	10	.5000	.94281	.29814	-.1744	1.1744	.00	3.00
	30 CH	10	.8500	.52967	.16750	.4711	1.2289	.00	1.50
	200 CH	10	.7000	1.05935	.33500	-.0578	1.4578	-1.00	2.50
	Total	30	.6833	.85585	.15626	.3638	1.0029	-1.00	3.00
Itchiness_0 - Itchiness: First Half	Control	10	.3000	.85635	.27080	-.3126	.9126	-1.00	2.00
	30 CH	8	.5625	.49552	.17519	.1482	.9768	.00	1.50
	200 CH	10	.1500	.57975	.18333	-.2647	.5647	-1.00	1.00
	Total	28	.3214	.66964	.12655	.0618	.5811	-1.00	2.00

Ranks			
	Group	**N**	**Mean Rank**
Rhinorrhoea_0 - Rhinorrhoea: First Half	**Control**	10	9.55
	30 CH	8	19.63
	200 CH	10	15.35
	Total	28	
Nose_0 - Nose: First Half	**Control**	10	14.70
	30 CH	9	18.89
	200 CH	10	11.80
	Total	29	
Sneezing_0 - Sneezing: First Half	**Control**	10	12.10
	30 CH	8	16.38
	200 CH	10	15.40
	Total	28	
Eyes_0 - Eyes: First Half	**Control**	10	12.15
	30 CH	10	18.80
	200 CH	10	15.55
	Total	30	
Itchiness_0 - Itchiness: First Half	**Control**	10	13.25
	30 CH	8	18.44
	200 CH	10	12.60
	Total	28	

Test Statistics(a,b)			
	Chi-Square	**df**	**Asymp. Sig.**
Rhinorrhoea_0 - Rhinorrhoea: First Half	7.198	2	.027
Nose_0 - Nose: First Half	3.624	2	.163
Sneezing_0 - Sneezing: First Half	1.415	2	.493
Eyes_0 - Eyes: First Half	3.035	2	.219
Itchiness_0 - Itchiness: First Half	3.005	2	.223
a Kruskal Wallis Test			
b Grouping Variable: Group			

Second Difference

Descriptives

		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
						Lower Bound	Upper Bound		
Rhinorrhoea_0 - Rhinorrhoea: Second Half	Control	10	.9000	.80966	.25604	.3208	1.4792	.00	2.50
	30 CH	8	1.7500	1.43925	.50885	.5468	2.9532	.00	3.50
	200 CH	10	1.7000	.94868	.30000	1.0214	2.3786	.00	3.00
	Total	28	1.4286	1.10315	.20848	1.0008	1.8563	.00	3.50
Nose_0 – Nose: Second Half	Control	10	.9000	1.12546	.35590	.0949	1.7051	-.50	2.50
	30 CH	9	1.5556	.84574	.28191	.9055	2.2056	.00	3.00
	200 CH	10	.5500	.86442	.27335	-.0684	1.1684	-.50	2.00
	Total	29	.9828	1.01315	.18814	.5974	1.3681	-.50	3.00
Sneezing_0 - Sneezing: Second Half	Control	10	2.2000	1.20646	.38152	1.3369	3.0631	.50	3.50
	30 CH	8	2.6250	1.09381	.38672	1.7105	3.5395	1.00	4.00
	200 CH	10	1.9000	1.07497	.33993	1.1310	2.6690	.00	3.50
	Total	28	2.2143	1.12570	.21274	1.7778	2.6508	.00	4.00
Eyes_0 - Eyes: Second Half	Control	10	1.1500	.91439	.28916	.4959	1.8041	.00	3.50
	30 CH	10	1.7000	1.05935	.33500	.9422	2.4578	.00	3.00
	200 CH	10	1.4000	1.41028	.44597	.3911	2.4089	-1.00	3.50
	Total	30	1.4167	1.13018	.20634	.9947	1.8387	-1.00	3.50
Itchiness_0 - Itchiness: Second Half	Control	10	1.0000	1.08012	.34157	.2273	1.7727	.00	3.00
	30 CH	8	1.3125	.79899	.28249	.6445	1.9805	.00	2.50
	200 CH	10	.7000	1.03280	.32660	-.0388	1.4388	.00	3.00
	Total	28	.9821	.98585	.18631	.5999	1.3644	.00	3.00

Ranks			
	Group	N	Mean Rank
Rhinorrhoea_0 - Rhinorrhoea: Second Half	Control	10	10.85
	30 CH	8	16.50
	200 CH	10	16.55
	Total	28	
Nose_0 - Nose: Second Half	Control	10	14.35
	30 CH	9	19.39
	200 CH	10	11.70
	Total	29	
Sneezing_0 - Sneezing: Second Half	Control	10	14.40
	30 CH	8	17.31
	200 CH	10	12.35
	Total	28	
Eyes_0 - Eyes: Second Half	Control	10	12.60
	30 CH	10	18.10
	200 CH	10	15.80
	Total	30	
Itchiness_0 - Itchiness: Second Half	Control	10	14.55
	30 CH	8	17.88
	200 CH	10	11.75
	Total	28	

Test Statistics(a,b)			
	Chi-Square	df	Asymp. Sig.
Rhinorrhoea_0 - Rhinorrhoea: Second Half	3.127	2	.209
Nose_0 - Nose: Second Half	4.175	2	.124
Sneezing_0 - Sneezing: Second Half	1.661	2	.436
Eyes_0 - Eyes: Second Half	2.058	2	.357
Itchiness_0 - Itchiness: Second Half	2.650	2	.266
a Kruskal Wallis Test			
b Grouping Variable: Group			

Third Difference

Descriptives

		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
						Lower Bound	Upper Bound		
Rhinorrhoea: First Half - Rhinorrhoea: Second Half	**Control**	10	.6000	.45947	.14530	.2713	.9287	.00	1.50
	30 CH	8	.4375	1.47449	.52131	-.7952	1.6702	-1.50	3.00
	200 CH	10	1.0000	.70711	.22361	.4942	1.5058	.00	2.50
	Total	28	.6964	.92636	.17506	.3372	1.0556	-1.50	3.00
Nose: First Half - Nose: Second Half	**Control**	10	.6000	.61464	.19437	.1603	1.0397	.00	1.50
	30 CH	9	.7778	.61802	.20601	.3027	1.2528	.00	1.50
	200 CH	10	.3500	.57975	.18333	-.0647	.7647	-.50	1.50
	Total	29	.5690	.60834	.11297	.3376	.8004	-.50	1.50
Sneezing: First Half - Sneezing: Second Half	**Control**	10	1.1500	.88349	.27938	.5180	1.7820	.00	2.50
	30 CH	8	.8125	1.16305	.41120	-.1598	1.7848	-1.00	2.50
	200 CH	10	.4000	.65828	.20817	-.0709	.8709	-1.00	1.50
	Total	28	.7857	.92725	.17523	.4262	1.1453	-1.00	2.50
Eyes: First Half - Eyes: Second Half	**Control**	10	.6500	.41164	.13017	.3555	.9445	.00	1.00
	30 CH	10	.8500	1.13162	.35785	.0405	1.6595	-1.50	2.50
	200 CH	10	.7000	.53748	.16997	.3155	1.0845	.00	1.50
	Total	30	.7333	.73968	.13505	.4571	1.0095	-1.50	2.50
Itchiness: First Half - Itchiness: Second Half	**Control**	10	.7000	.53748	.16997	.3155	1.0845	.00	1.50
	30 CH	8	.7500	.59761	.21129	.2504	1.2496	.00	2.00
	200 CH	10	.5500	.79757	.25221	-.0205	1.1205	.00	2.50
	Total	28	.6607	.63906	.12077	.4129	.9085	.00	2.50

Ranks			
	Group	**N**	**Mean Rank**
Rhinorrhoea: First Half – Rhinorrhoea: Second Half	**Control**	10	13.10
	30 CH	8	12.75
	200 CH	10	17.30
	Total	28	
Nose: First Half - Nose: Second Half	**Control**	10	15.30
	30 CH	9	17.83
	200 CH	10	12.15
	Total	29	
Sneezing: First Half - Sneezing: Second Half	**Control**	10	17.45
	30 CH	8	14.63
	200 CH	10	11.45
	Total	28	
Eyes: First Half - Eyes: Second Half	**Control**	10	14.20
	30 CH	10	17.15
	200 CH	10	15.15
	Total	30	
Itchiness: First Half - Itchiness: Second Half	**Control**	10	15.90
	30 CH	8	15.75
	200 CH	10	12.10
	Total	28	

Test Statistics(a,b)			
	Chi-Square	**df**	**Asymp. Sig.**
Rhinorrhoea: First Half - Rhinorrhoea: Second Half	1.893	2	.388
Nose: First Half - Nose: Second Half	2.296	2	.317
Sneezing: First Half - Sneezing: Second Half	2.768	2	.251
Eyes: First Half - Eyes: Second Half	.629	2	.730
Itchiness: First Half - Itchiness: Second Half	1.442	2	.486
a Kruskal Wallis Test			
b Grouping Variable: Group			

APPENDIX G-2: STATISTICAL DATA USED FOR LINEAR GRAPHS

Descriptives (Percentages are worked from base (0) value)

		15	30	45	60	No in Group
Rhinorrhoea	Control	5.555555556	12.03703704	20.37037037	37.96296296	9
	30 CH	28.125	55.20833333	50	58.33333333	8
	200 CH	10	36.66666667	53.33333333	67.5	10
		15	30	45	60	
Nose	Control	1.388888889	6.944444444	43.05555556	56.94444444	6
	30 CH	16.66666667	44.79166667	59.375	67.70833333	8
	200 CH	11.9047619	15.47619048	9.523809524	35.71428571	7
		15	30	45	60	
Sneezing	Control	19.16666667	35	59.16666667	72.5	10
	30 CH	44.79166667	70.83333333	80.20833333	86.45833333	8
	200 CH	52.5	75.83333333	80	85	10
		15	30	45	60	
Eyes	Control	22.22222222	30.55555556	62.03703704	67.59259259	9
	30 CH	17.59259259	52.77777778	66.66666667	72.22222222	9
	200 CH	14.58333333	42.70833333	57.29166667	66.66666667	8
		15	30	45	60	
Itchiness	Control	-9.375	31.25	53.125	62.5	8
	30 CH	11.9047619	36.9047619	59.52380952	63.0952381	7
	200 CH	0	4.761904762	35.71428571	54.76190476	7

Note: In most cases the number of people in a group is not 10. This is due to those that did not fill in their questionnaire, or only filled in zero. I excluded the zero cases as this was thought not helpful, since the above values calculated are averages and should the zeros be added into the calculations it will reduce the percentage improvement averages.

APPENDIX G-3: WILCOX SIGNED RANKS TEST

SUMMARY

P-Values Within Groups:				
		Control	30CH	200CH
Rhinorrhoea	Initial vs First Half	**0.059**	**0.017**	**0.034**
	Initial vs Second Half	**0.011**	**0.027**	**0.007**
	First Half vs Second Half	**0.010**	0.443	**0.007**
Nose	Initial vs First Half	0.290	**0.008**	0.194
	Initial vs Second Half	**0.044**	**0.011**	**0.071**
	First Half vs Second Half	**0.026**	**0.016**	**0.084**
Sneezing	Initial vs First Half	**0.020**	**0.011**	**0.007**
	Initial vs Second Half	**0.005**	**0.012**	**0.007**
	First Half vs Second Half	**0.011**	**0.093**	**0.098**
Eyes	Initial vs First Half	**0.066**	**0.007**	**0.075**
	Initial vs Second Half	**0.006**	**0.010**	**0.020**
	First Half vs Second Half	**0.009**	**0.049**	**0.014**
Itchiness	Initial vs First Half	0.273	**0.024**	0.450
	Initial vs Second Half	**0.026**	**0.016**	**0.042**
	First Half vs Second Half	**0.014**	**0.016**	**0.041**

Key:	**First Difference = Initial minus First Half**
	Second Difference = Initial minus Second Half
	Third Difference = First Half minus Second Half

Control

Paired Samples Statistics					
		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Rhinorrhoea_0	2.80	10	1.317	.416
	Rhinorrhoea: First Half	2.5000	10	1.13039	.35746
Pair 2	Rhinorrhoea_0	2.80	10	1.317	.416
	Rhinorrhoea: Second Half	1.9000	10	.87560	.27689
Pair 3	Rhinorrhoea: First Half	2.5000	10	1.13039	.35746
	Rhinorrhoea: Second Half	1.9000	10	.87560	.27689
Pair 4	Nose_0	1.50	10	1.509	.477
	Nose: First Half	1.2000	10	1.22927	.38873
Pair 5	Nose_0	1.50	10	1.509	.477
	Nose: Second Half	.6000	10	.73786	.23333
Pair 6	Nose: First Half	1.2000	10	1.22927	.38873
	Nose: Second Half	.6000	10	.73786	.23333
Pair 7	Sneezing_0	3.20	10	.789	.249
	Sneezing: First Half	2.1500	10	.66875	.21148
Pair 8	Sneezing_0	3.20	10	.789	.249
	Sneezing: Second Half	1.0000	10	.70711	.22361
Pair 9	Sneezing: First Half	2.1500	10	.66875	.21148
	Sneezing: Second Half	1.0000	10	.70711	.22361
Pair 10	Eyes_0	2.00	10	1.333	.422
	Eyes: First Half	1.5000	10	1.20185	.38006
Pair 11	Eyes_0	2.00	10	1.333	.422
	Eyes: Second Half	.8500	10	.91439	.28916
Pair 12	Eyes: First Half	1.5000	10	1.20185	.38006
	Eyes: Second Half	.8500	10	.91439	.28916
Pair 13	Itchiness_0	1.70	10	1.418	.448
	Itchiness: First Half	1.4000	10	1.04881	.33166
Pair 14	Itchiness_0	1.70	10	1.418	.448
	Itchiness: Second Half	.7000	10	.71492	.22608
Pair 15	Itchiness: First Half	1.4000	10	1.04881	.33166
	Itchiness: Second Half	.7000	10	.71492	.22608

Ranks				
		N	Mean Rank	Sum of Ranks
Rhinorrhoea: First Half Rhinorrhoea_0	Negative Ranks	4	2.50	10.00
	Positive Ranks	0	.00	.00
	Ties	6		
	Total	10		
Rhinorrhoea: Second Half Rhinorrhoea_0	Negative Ranks	8	4.50	36.00
	Positive Ranks	0	.00	.00
	Ties	2		
	Total	10		
Rhinorrhoea: Second Half Rhinorrhoea: First Half	Negative Ranks	8	4.50	36.00
	Positive Ranks	0	.00	.00
	Ties	2		
	Total	10		
Nose: First Half Nose_0	Negative Ranks	5	3.10	15.50
	Positive Ranks	1	5.50	5.50
	Ties	4		
	Total	10		
Nose: Second Half Nose_0	Negative Ranks	5	4.00	20.00
	Positive Ranks	1	1.00	1.00
	Ties	4		
	Total	10		
Nose: Second Half Nose: First Half	Negative Ranks	6	3.50	21.00
	Positive Ranks	0	.00	.00
	Ties	4		
	Total	10		
Sneezing: First Half Sneezing_0	Negative Ranks	7	4.93	34.50
	Positive Ranks	1	1.50	1.50
	Ties	2		
	Total	10		
Sneezing: Second Half Sneezing_0	Negative Ranks	10	5.50	55.00
	Positive Ranks	0	.00	.00
	Ties	0		
	Total	10		

Sneezing: Second Half Sneezing: First Half	**Negative Ranks**	8	4.50	36.00
	Positive Ranks	0	.00	.00
	Ties	2		
	Total	10		
Eyes: First Half Eyes_0	**Negative Ranks**	4	2.50	10.00
	Positive Ranks	0	.00	.00
	Ties	6		
	Total	10		
Eyes: Second Half Eyes_0	**Negative Ranks**	9	5.00	45.00
	Positive Ranks	0	.00	.00
	Ties	1		
	Total	10		
Eyes: Second Half Eyes: First Half	**Negative Ranks**	8	4.50	36.00
	Positive Ranks	0	.00	.00
	Ties	2		
	Total	10		
Itchiness: First Half Itchiness_0	**Negative Ranks**	3	2.67	8.00
	Positive Ranks	1	2.00	2.00
	Ties	6		
	Total	10		
Itchiness: Second Half Itchiness_0	**Negative Ranks**	6	3.50	21.00
	Positive Ranks	0	.00	.00
	Ties	4		
	Total	10		
Itchiness: Second Half Itchiness: First Half	**Negative Ranks**	7	4.00	28.00
	Positive Ranks	0	.00	.00
	Ties	3		
	Total	10		

Test Statistics(b)		
	Z	**Asymp. Sig. (2-tailed)**
Rhinorrhoea: First Half – Rhinorrhoea_0	-1.890(a)	.059
Rhinorrhoea: Second Half - Rhinorrhoea_0	-2.546(a)	.011
Rhinorrhoea: Second Half - Rhinorrhoea: First Half	-2.588(a)	.010
Nose: First Half - Nose_0	-1.057(a)	.290
Nose: Second Half - Nose_0	-2.014(a)	.044
Nose: Second Half - Nose: First Half	-2.220(a)	.026
Sneezing: First Half - Sneezing_0	-2.319(a)	.020
Sneezing: Second Half - Sneezing_0	-2.825(a)	.005
Sneezing: Second Half - Sneezing: First Half	-2.530(a)	.011
Eyes: First Half - Eyes_0	-1.841(a)	.066
Eyes: Second Half - Eyes_0	-2.751(a)	.006
Eyes: Second Half - Eyes: First Half	-2.598(a)	.009
Itchiness: First Half - Itchiness_0	-1.095(a)	.273
Itchiness: Second Half - Itchiness_0	-2.226(a)	.026
Itchiness: Second Half - Itchiness: First Half	-2.456(a)	.014
a Based on positive ranks.		
b Wilcoxon Signed Ranks Test		

30 CH

Paired Samples Statistics					
		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Rhinorrhoea_0	3.00	8	.926	.327
	Rhinorrhoea: First Half	1.6875	8	1.09992	.38888
Pair 2	Rhinorrhoea_0	3.00	8	.926	.327
	Rhinorrhoea: Second Half	1.2500	8	1.33631	.47246
Pair 3	Rhinorrhoea: First Half	1.6875	8	1.09992	.38888
	Rhinorrhoea: Second Half	1.2500	8	1.33631	.47246
Pair 4	Nose_0	2.56	9	1.130	.377
	Nose: First Half	1.7778	9	1.17556	.39185
Pair 5	Nose_0	2.56	9	1.130	.377
	Nose: Second Half	1.0000	9	.96825	.32275
Pair 6	Nose: First Half	1.7778	9	1.17556	.39185
	Nose: Second Half	1.0000	9	.96825	.32275
Pair 7	Sneezing_0	3.25	8	1.035	.366
	Sneezing: First Half	1.4375	8	1.29387	.45745
Pair 8	Sneezing_0	3.25	8	1.035	.366
	Sneezing: Second Half	.6250	8	.95431	.33740
Pair 9	Sneezing: First Half	1.4375	8	1.29387	.45745
	Sneezing: Second Half	.6250	8	.95431	.33740
Pair 10	Eyes_0	2.60	10	1.174	.371
	Eyes: First Half	1.7500	10	1.06066	.33541
Pair 11	Eyes_0	2.60	10	1.174	.371
	Eyes: Second Half	.9000	10	1.10050	.34801
Pair 12	Eyes: First Half	1.7500	10	1.06066	.33541
	Eyes: Second Half	.9000	10	1.10050	.34801
Pair 13	Itchiness_0	2.38	8	1.302	.460
	Itchiness: First Half	1.8125	8	1.19336	.42192
Pair 14	Itchiness_0	2.38	8	1.302	.460
	Itchiness: Second Half	1.0625	8	.94255	.33324
Pair 15	Itchiness: First Half	1.8125	8	1.19336	.42192
	Itchiness: Second Half	1.0625	8	.94255	.33324

Ranks				
		N	Mean Rank	Sum of Ranks
Rhinorrhoea: First Half Rhinorrhoea_0	Negative Ranks	7	4.00	28.00
	Positive Ranks	0	.00	.00
	Ties	1		
	Total	8		
Rhinorrhoea: Second Half Rhinorrhoea_0	Negative Ranks	6	3.50	21.00
	Positive Ranks	0	.00	.00
	Ties	2		
	Total	8		
Rhinorrhoea: Second Half Rhinorrhoea: First Half	Negative Ranks	4	4.63	18.50
	Positive Ranks	3	3.17	9.50
	Ties	1		
	Total	8		
Nose: First Half Nose_0	Negative Ranks	8	4.50	36.00
	Positive Ranks	0	.00	.00
	Ties	1		
	Total	9		
Nose: Second Half Nose_0	Negative Ranks	8	4.50	36.00
	Positive Ranks	0	.00	.00
	Ties	1		
	Total	9		
Nose: Second Half Nose: First Half	Negative Ranks	7	4.00	28.00
	Positive Ranks	0	.00	.00
	Ties	2		
	Total	9		
Sneezing: First Half Sneezing_0	Negative Ranks	8	4.50	36.00
	Positive Ranks	0	.00	.00
	Ties	0		
	Total	8		
Sneezing: Second Half Sneezing_0	Negative Ranks	8	4.50	36.00
	Positive Ranks	0	.00	.00
	Ties	0		
	Total	8		

Sneezing: Second Half Sneezing: First Half	**Negative Ranks**	5	3.70	18.50
	Positive Ranks	1	2.50	2.50
	Ties	2		
	Total	8		
Eyes: First Half Eyes_0	**Negative Ranks**	9	5.00	45.00
	Positive Ranks	0	.00	.00
	Ties	1		
	Total	10		
Eyes: Second Half Eyes_0	**Negative Ranks**	8	4.50	36.00
	Positive Ranks	0	.00	.00
	Ties	2		
	Total	10		
Eyes: Second Half Eyes: First Half	**Negative Ranks**	8	4.88	39.00
	Positive Ranks	1	6.00	6.00
	Ties	1		
	Total	10		
Itchiness: First Half Itchiness_0	**Negative Ranks**	6	3.50	21.00
	Positive Ranks	0	.00	.00
	Ties	2		
	Total	8		
Itchiness: Second Half Itchiness_0	**Negative Ranks**	7	4.00	28.00
	Positive Ranks	0	.00	.00
	Ties	1		
	Total	8		
Itchiness: Second Half Itchiness: First Half	**Negative Ranks**	7	4.00	28.00
	Positive Ranks	0	.00	.00
	Ties	1		
	Total	8		

Test Statistics(b)		
	Z	**Asymp. Sig. (2-tailed)**
Rhinorrhoea: First Half – Rhinorrhoea_0	-2.388(a)	.017
Rhinorrhoea: Second Half - Rhinorrhoea_0	-2.207(a)	.027
Rhinorrhoea: Second Half - Rhinorrhoea: First Half	-.768(a)	.443
Nose: First Half - Nose_0	-2.636(a)	.008
Nose: Second Half - Nose_0	-2.539(a)	.011
Nose: Second Half - Nose: First Half	-2.401(a)	.016
Sneezing: First Half - Sneezing_0	-2.533(a)	.011
Sneezing: Second Half - Sneezing_0	-2.527(a)	.012
Sneezing: Second Half - Sneezing: First Half	-1.682(a)	.093
Eyes: First Half - Eyes_0	-2.701(a)	.007
Eyes: Second Half - Eyes_0	-2.588(a)	.010
Eyes: Second Half - Eyes: First Half	-1.969(a)	.049
Itchiness: First Half - Itchiness_0	-2.264(a)	.024
Itchiness: Second Half - Itchiness_0	-2.414(a)	.016
Itchiness: Second Half - Itchiness: First Half	-2.414(a)	.016
a Based on positive ranks.		
b Wilcoxon Signed Ranks Test		

200 CH

Paired Samples Statistics					
		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Rhinorrhoea_0	2.80	10	.919	.291
	Rhinorrhoea: First Half	2.1000	10	.80966	.25604
Pair 2	Rhinorrhoea_0	2.80	10	.919	.291
	Rhinorrhoea: Second Half	1.1000	10	.73786	.23333
Pair 3	Rhinorrhoea: First Half	2.1000	10	.80966	.25604
	Rhinorrhoea: Second Half	1.1000	10	.73786	.23333
Pair 4	Nose_0	1.70	10	1.418	.448
	Nose: First Half	1.5000	10	1.20185	.38006
Pair 5	Nose_0	1.70	10	1.418	.448
	Nose: Second Half	1.1500	10	.91439	.28916
Pair 6	Nose: First Half	1.5000	10	1.20185	.38006
	Nose: Second Half	1.1500	10	.91439	.28916
Pair 7	Sneezing_0	2.50	10	1.080	.342
	Sneezing: First Half	1.0000	10	1.20185	.38006
Pair 8	Sneezing_0	2.50	10	1.080	.342
	Sneezing: Second Half	.6000	10	1.14988	.36362
Pair 9	Sneezing: First Half	1.0000	10	1.20185	.38006
	Sneezing: Second Half	.6000	10	1.14988	.36362
Pair 10	Eyes_0	2.30	10	1.337	.423
	Eyes: First Half	1.6000	10	1.22020	.38586
Pair 11	Eyes_0	2.30	10	1.337	.423
	Eyes: Second Half	.9000	10	1.26491	.40000
Pair 12	Eyes: First Half	1.6000	10	1.22020	.38586
	Eyes: Second Half	.9000	10	1.26491	.40000
Pair 13	Itchiness_0	1.50	10	1.269	.401
	Itchiness: First Half	1.3500	10	1.20301	.38042
Pair 14	Itchiness_0	1.50	10	1.269	.401
	Itchiness: Second Half	.8000	10	1.11056	.35119
Pair 15	Itchiness: First Half	1.3500	10	1.20301	.38042
	Itchiness: Second Half	.8000	10	1.11056	.35119

Ranks				
Rhinorrhoea: First Half Rhinorrhoea_0		**N**	**Mean Rank**	**Sum of Ranks**
Rhinorrhoea: Second Half Rhinorrhoea_0	**Negative Ranks**	8	5.00	40.00
	Positive Ranks	1	5.00	5.00
	Ties	1		
	Total	10		
Rhinorrhoea: Second Half Rhinorrhoea: First Half	**Negative Ranks**	9	5.00	45.00
	Positive Ranks	0	.00	.00
	Ties	1		
	Total	10		
Nose: First Half Nose_0	**Negative Ranks**	9	5.00	45.00
	Positive Ranks	0	.00	.00
	Ties	1		
	Total	10		
Nose: Second Half Nose_0	**Negative Ranks**	3	2.83	8.50
	Positive Ranks	1	1.50	1.50
	Ties	6		
	Total	10		
Nose: Second Half Nose: First Half	**Negative Ranks**	5	3.80	19.00
	Positive Ranks	1	2.00	2.00
	Ties	4		
	Total	10		
Sneezing: First Half Sneezing_0	**Negative Ranks**	5	3.70	18.50
	Positive Ranks	1	2.50	2.50
	Ties	4		
	Total	10		
Sneezing: Second Half Sneezing_0	**Negative Ranks**	9	5.00	45.00
	Positive Ranks	0	.00	.00
	Ties	1		
	Total	10		
Sneezing: Second Half Sneezing: First Half	**Negative Ranks**	9	5.00	45.00
	Positive Ranks	0	.00	.00
	Ties	1		
	Total	10		

Eyes: First Half Eyes_0	**Negative Ranks**	7	4.21	29.50
	Positive Ranks	1	6.50	6.50
	Ties	2		
	Total	10		
Eyes: Second Half Eyes_0	**Negative Ranks**	6	4.08	24.50
	Positive Ranks	1	3.50	3.50
	Ties	3		
	Total	10		
Eyes: Second Half Eyes: First Half	**Negative Ranks**	7	4.93	34.50
	Positive Ranks	1	1.50	1.50
	Ties	2		
	Total	10		
Itchiness: First Half Itchiness_0	**Negative Ranks**	7	4.00	28.00
	Positive Ranks	0	.00	.00
	Ties	3		
	Total	10		
Itchiness: Second Half Itchiness_0	**Negative Ranks**	3	2.33	7.00
	Positive Ranks	1	3.00	3.00
	Ties	6		
	Total	10		
Itchiness: Second Half Itchiness: First Half	**Negative Ranks**	5	3.00	15.00
	Positive Ranks	0	.00	.00
	Ties	5		
	Total	10		
	Negative Ranks	5	3.00	15.00
	Positive Ranks	0	.00	.00
	Ties	5		
	Total	10		

Test Statistics(b)		
	Z	**Asymp. Sig. (2-tailed)**
Rhinorrhoea: First Half – Rhinorrhoea_0	-2.114(a)	.034
Rhinorrhoea: Second Half - Rhinorrhoea_0	-2.677(a)	.007
Rhinorrhoea: Second Half - Rhinorrhoea: First Half	-2.687(a)	.007
Nose: First Half - Nose_0	-1.300(a)	.194
Nose: Second Half – Nose_0	-1.807(a)	.071
Nose: Second Half – Nose: First Half	-1.725(a)	.084
Sneezing: First Half - Sneezing_0	-2.680(a)	.007
Sneezing: Second Half - Sneezing_0	-2.680(a)	.007
Sneezing: Second Half - Sneezing: First Half	-1.653(a)	.098
Eyes: First Half - Eyes_0	-1.781(a)	.075
Eyes: Second Half – Eyes_0	-2.325(a)	.020
Eyes: Second Half – Eyes: First Half	-2.456(a)	.014
Itchiness: First Half - Itchiness_0	-.756(a)	.450
Itchiness: Second Half - Itchiness_0	-2.032(a)	.042
Itchiness: Second Half - Itchiness: First Half	-2.041(a)	.041
a Based on positive ranks.		
b Wilcoxon Signed Ranks Test		

APPENDIX H: STANDARDIZED QUESTIONNAIRE FOR SFAR ASSESMENT

Standardized questionnaire for SFAR assessment

1 In the past 12 months, have you had a problem apart from cold or flu with (please tick the appropriate cases(s))

Sneezing	NO	☐	YES	☐
Runny nose	NO	☐	YES	☐
Blocked nose	NO	☐	YES	☐

If YES (at least one nose problem)

2 In the past 12 months, has this nose problem been accompanied by itchy-watery eyes?

NO ☐ YES ☐

3 In which of the past 12 months (or in which season) did this nose problem occur?

Jan ☐ Feb ☐ Mar ☐

April ☐ May ☐ June ☐

July ☐ Aug ☐ Sept ☐

Oct ☐ Nov ☐ Dec ☐

(or alternatively)
Winter ☐ Spring ☐ Summer ☐ Autumn ☐

4 What trigger factors provoke or increase your nose problems?

House dust ☐

House dust mites ☐

Pollens ☐

Animals (cats, dogs....) ☐

Other (please specify) _____

5 Do you think you suffer from allergies?

NO ☐ YES ☐

6 Have you already been tested for allergies (SPT,IgE)?

NO ☐ YES ☐

(if YES)

6a What were the results?

Negative ☐ Positive ☐

7 Has a doctor already diagnosed that you suffer/ suffered from asthma, eczema or allergic rhinitis?

NO ☐ YES ☐

8 Does any member of your family suffer from asthma, eczema or allergic rhinitis?

NO ☐ YES ☐

(If YES: Whom and what disease? (please tick appropriate cases(s))

Father	Asthma	☐	Eczema	☐	Allergic rhinitis	☐
Mother	Asthma	☐	Eczema	☐	Allergic rhinitis	☐
Siblings	Asthma	☐	Eczema	☐	Allergic rhinitis	☐