THE EFFICACY OF A HOMOEOPATHIC *Similasan Nasal Allergy Relief Spray*® IN THE MANAGEMENT OF ALLERGIC RHINITIS IN TERMS OF THE CARAT QUESTIONNAIRE

By

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ABSTRACT

Allergic rhinitis (AR) is a symptomatic disorder of the nose characterized by inflammation of the nasal mucosa. It consists of a group of disorders that are all typified by the presence of one or more of the following: nasal itching, congestion, sneezing and rhinorrhoea (Wallace *et. al.,* 2008). Allergic rhinitis can result in decreased quality of life, decreased sleep quantity, obstructive sleep apnoea and impaired performance at work and school (Blaiss, 2010: 375-380).

According to Small and Kim (2011) allergic rhinitis (AR) is the most common allergic condition and one of the most common of all minor afflictions. It affects between 10-20% of all people in the United States, and the prevalence of the disorder is increasing. This may result in significant impairment to quality of life, sleep and work performance (Small and Kim 2011). A therapeutic goal for patients suffering from allergic rhinitis is to prevent or minimise symptoms, using treatment with minimal effects or no side effects and of reasonable expenses, so that patients may maintain a normal life style (DiPiro*et al.*2002).

Homoeopathy is a complete system of medicine developed by German physician and chemist, Dr Samuel Hahnemann (1755-1843). It is based on the following theories, first the doctrine of signature that disease is curable by those drugs which produce effect on the body similar to the symptoms of the disease *“similia similibus currantur”*; second that the effects of the drug are increased by giving it in a minute dose, which is obtained by dilution or trituration to an extreme limit and thirdly the notion that chronic disease are only manifestation of suppressed itch or psora (Ernst 2016). *Similasan Nasal Allergy Relief Spray*® is commercially available as a homoeopathic nasal spray. It is based on the principle of "let likes cure likes" or the Law of Similars. According to the company, this product is 100% natural, and contains active ingredients with non-drowsy effects which relieves allergic congestion, itching and runny nose, and it is preservative free (Similasan Corporation 1999-2015). *Similasan Nasal Allergy ReliefSpray*® mist gently stimulates the body's natural ability to relieve allergic congestion, itchy, runny nose and rhinitis caused by pollen, pet dander, dust and mould spores. Furthermore, the *Similasan Nasal Allergy ReliefSpray*® mists is non-habit forming and will not cause reliance or a rebound

effect. The ingredients are: *Cardiospermum 6X, Galphimiaglauca 6X, Luffa operculata 6X, Sabadilla 6X* (SimilasanCoorporation 1999-2015).

The aim of this double-blind randomised controlled study is to determine the efficacy of the homoeopathic *Similasan Nasal Allergy Relief Spray*® in the management of allergic rhinitis. Outcomes were monitored using questionnaires and a daily log book.

This was a quantitative study which included thirty participants suffering from allergic rhinitis. Participants volunteered to participate in the study, were over the age of eighteen and consented to the procedure of the study. Participants involved in the research study were randomly divided into treatment group and placebo group. The treatment group received *Similasan Nasal Allergy Relief Spray*® and the placebo group received a saline nasal spray.

The research study was conducted over a period of four weeks at the Durban University of Technology Homoeopathic Day Clinic. Participants were instructed to rate their symptoms before, during and after taking treatment (Appendix, C and D).
The parametric test used in this study was Independent Samples T- Test. Non-parametric tests included ANOVA and Pearson chi-square.

Rhinorrhoea, sneezing, itching of the eyes and nasal congestion showed a statistically significant results but some of the participant's symptoms deteriorated after a period of improvement. This research determined that *Similisan Nasal Allergy Relief Spray* ® didn't have a significant effect in treating allergic rhinitis in terms of the CARAT questionnaire.

DECLARATION

I, Thobile Tshabalala, do declare that this dissertation is representative of my own work, both in conception and execution, unless explicitly acknowledged (including citation of published and unpublished sources). The work has not previously submitted in any form to Durban University of Technology or to any institution for assessment or any other purpose.

APPROVED FOR FINAL SUBMISSION

Student Signature	Date
Dr. I Couchman MTech: Homoeopathy	Date
Dr. S Nienaber MTech: Homoeopathy	Date

DEDICATION

I dedicate this work to:

First of all, to the Almighty God for giving me strength as 2 Corinthians 12:7-10 "… when I am weak then I am strong…"

My parents Amos and Liketso Tshabalalala, words cannot express my gratitude, for the years of support and dedication you have shown to my education. I cannot thank you enough for all the love and guidance you have shown me throughout my studying and most importantly through my life. It is because of you that I have a feature to be excited and proud of...Ngiyabonga mama nobaba….

My siblings (Thandokuhle, Refiloe, Thabsile and Tshidiso), thank you for your support guidance and advice. In times when I thought I could not make it you encouraged me to go on. Thank you for being the rock that I could stand on.

And lastly to my son Thembalihle thank you for understanding when mommy was not around.

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- To the friends I made during my years of study thank you for the love and friendship

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GLOSSARY OF TERMS

Atopic disease

From Greek atopy means “out of place”, is associated with the production of specific IgE antibodies in response to common environmental proteins such as house dustmite, grass pollen and food allergens (Pascual and Roa 2013).

Allergy

A state of hypersensitivity induced by exposure to a particular antigen resulting in harmful immunologic reactions on subsequent exposures (The Encyclopaedia Britannica Inc. 2017).

Anthropogenic

Adverse effects of human activities on estuarine environments (Mann 2009).

Endotoxin

A toxic substance bound to the bacterial cell wall and released when the bacterium ruptures or disintegrates. Endotoxins consist of lipopolysaccharide and lipoprotein complex. The protein component determines its foreign nature. Endotoxins are rarely fatal, although they often cause fever (The Encyclopaedia Britannica Inc. 2017).

Homoeopathic complex

Is a mixture or combination of remedies, selected on the bases mainly on the symptoms of patients (Reckeweg 2002).

Similimum

This is the medication that matches the presenting symptoms picture of the patient most accurately. A homoeopath observes the patient and takes into consideration the patient`s characters, stress level, level of exerciser, diet, food preference, family history, sleep pattern and general effects to obtain a unique symptom picture and then that is matched to a remedy (the similimum) (Lockie and Geddes 2001).

CHAPTER 1 – OVERVIEW OF THE STUDY

1.1 INTRODUCTION

Allergic rhinitis is a symptomatic disorder of the nose characterized by inflammation of nasal mucosa. It consists of a group of disorders that are all typified by the presence of one or more of the following: nasal itching, congestion, sneezing and rhinorrhoea (Wallace *et. al.* 2008). Allergic rhinitis can result in decreased quality of life, decreased sleep quantity, obstructive sleep apnoea and impaired performance at work and school (Blaiss 2010).

According to Small and Kim (2011), allergic rhinitis is the most common allergic condition and one of the most common of all minor afflictions. Antihistamine, nasal corticosteroids sprays, decongestants and leukotriene have adverse reactions that cause sedation, disturbance of the central nervous system, rebound and immune suppressive effects (Greiner and Meltzer 2006).

There has been evidential support that homoeopathic remedies are effective in treating allergic rhinitis (Arthur 2009; Goossens *et al.* 2009; Taylor *et al.*2000; Ullman and Frass, 2010; Naidoo and Pellow 2013).Homoeopathic medicine may produce additional symptoms during the course of the treatment, but these are rarely serious or harmful and may disappear quickly, this phenomena is called Homoeopathic aggravation (Hahnemann 2011).Homoeopathy attempts to bring each individual to the highest level of health possible on the physical, mental and emotional level by eliminating and healing the underlying susceptibility of developing of a disease state (Ullman 1995). A similar study was conducted at the University of Johannesburg evaluating the effect of Luffeel nasal spray® and Luffeel tablets® in combination using Phadiatop® test, RAST inhalant screens subjective to evaluate the symptoms of allergic rhinitis in varying degrees (Arthur 2009).

Allergic rhinitis is a global health problem, affecting 500 million patients world-wide. It affects between 10-20% of all people in the United States and the prevalence of the disorder is increasing. South Africa shows a persistent form of allergic rhinitis that leads to chronic otitis media and sinusitis that is seen in 35-40% of cases particularly

in young children (Green *et al*. 2012). This result in significant impairment to the quality of life, sleep and work performance (Small and Kim 2011).

Similasan® products have been researched and shown to be capable of reducing symptoms by administrating the substance in low dilutions as homoeopathically prepared medicine (Similisan 2015). This study did not only focus on the symptoms of allergic rhinitis but also on the quality of life due to the fact that allergic rhinitis can restrict them from doing their daily activity.

1.2 AIM OF THE STUDY

The aim of this study is to determine the efficacy of homoeopathic *Similasan Nasal Allergy Relief Spray*® in the management of allergic rhinitis in terms of CARAT questionnaire and a daily log book.

1.3 IMPORTANCE OF THE PROBLEM

According to Braido *et al.* (2014), hundreds of millions of subjects in the world suffer from rhinitis and this negatively impacts the socio-economic welfare of society.

In South Africa, allergic rhinitis is more commonly of the persistent type, particularly in the Highveld regions, because grass pollens are present for significant periods of time in the atmosphere. It is expected that allergic problems will increase further as air pollution and the ambient temperature increases (Pawankar *et al.* 2011). House dust mites, grass, pets, fungal spores and cockroaches account for over 80% of allergies in allergic rhinitis patients in South Africa (Butler 2009).

As stated by Amato *et al.* (2010) and Tamay *et al.* (2007), the rising incidence of allergic rhinitis is thought to be the result of the environmental toxins, abnormalities in the immune system and life style factors such as diet, medication, preservatives, additives and stress. Untreated allergic rhinitis can affect the physical and psychological wellbeing of a person, as well as their capacity to function.

Complications of untreated allergic rhinitis include asthma, sinusitis, otitis media, nasal polyps and other lower respiratory tract infections (Lakhani, North and Ellis 2012).

1.4 OBJECTIVES OF THE STUDY

1.4.1 THE FIRST OBJECTIVE

To determine the efficacy of a homoeopathic *Similasan Nasal Allergy Relief Spray*® in the management of allergic rhinitis in terms of the CARAT questionnaire (Appendix D).

1.4.2 THE SECOND OBJECTIVE

To determine the efficacy of *Similasan Nasal Allergy Relief Spray*® in the management of allergic rhinitis in terms of the daily log records using individual symptoms of allergic rhinitis such as nasal itching, sneezing, congestion, discharge, ocular redness and itching as overall indicator, over the period of 4 weeks of intervention (Appendix C).

1.5 STATEMENT OF HYPOTHESIS

1.5.1 THE FIRST HYPOTHESIS

It is hypothesised that *Similasan Nasal Allergy Relief Spray*® will have beneficial effects in allergic rhinitis as shown in the CARAT questionnaire (refer Appendix D), to decrease the symptoms of allergic rhinitis when compared to the placebo group.

1.5.2 THE SECOND HYPOTHESIS

It is hypothesised that *Similasan Nasal Allergy Relief Spray*® will have beneficial effect in allergic rhinitis as shown in the use of daily log books (refer Appendix C), to decrease the symptoms of allergic rhinitis when compared to the placebo group.

CHAPTER 2 - LITERATURE REVIEW

2.1 ANATOMY AND PHYSIOLOGY OF THE NOSE

The main function of the nose is to smell, breath, filtrate dust, inspire humidified air before reaching the lungs and eliminate secretion from nasolacrimal ducts and paranasal sinuses (Moore *et al.* 2013). The nose provides defensive and homeostatic functions requiring rapid response to physical and chemical stimuli (Sarin *et al.*2006).

The external nose consists of paired nasal bones and the upper and lower lateral cartilages. Internally, the nasal septum divides the nasal cavity into the right and left side. The lateral nasal wall consists of the inferior and middle turbinate bones (Moore *et al.*2013). Tubercle of the incoming air is created by the meatuses which allow the dirt particles to come into contact with mucus. This promotes filtration, humidifying and warming of incoming air (Martini 2006). The nasal cavity and the paranasal sinuses are covered by a pseudostratified columnar ciliatedepithelium with goblet cells. The goblets cells secrete mucus that may enter the nasal cavity and, together with the cilia this traps foreign particles (Pfaar *et al.* 2009; Young *et al.*2013). Olfactory cells pass through the cribiform plate and the olfactory bulb to form the olfactory nerve which contains receptors specifically for sense of smell (Moore *et al.*2013).

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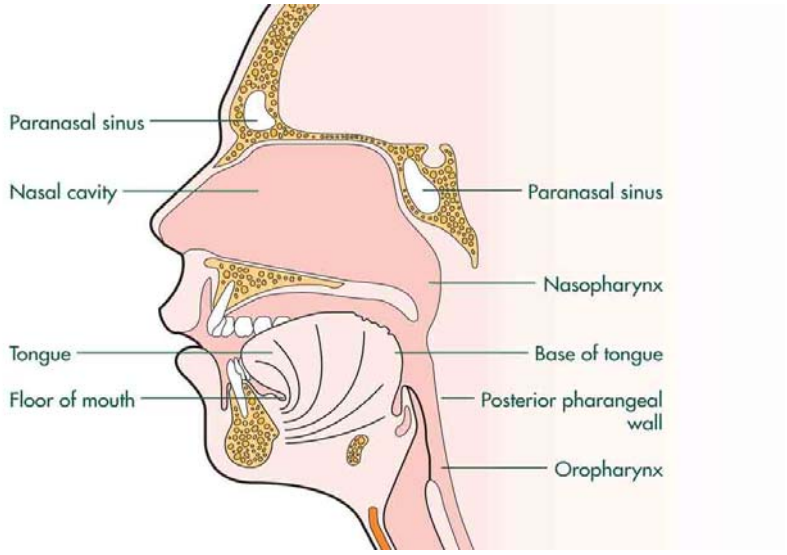

Figure 2-1 Anatomy of the nose (Source: Health Life Media Team© 2016)

2.2 INTRODUCTION TO THE IMMUNE SYSTEM

The immune system consists of an intricately linked network of cells, proteins and lymphoid organs which are strategically placed to ensure maximal protection against infection. Immune defence is categorised into an innate immune response and adaptive/acquired immune response (Colledge *et al.*2010).

- The *innate immune* system provides the first line of defence against microorganism and control bacterial infection. It is mediated by cells such asphagocytic cells, natural killer (NK) cells and proteins that are always present and have an immediate response to fight against the entry of microbes or infection. These include macrophages, poly-morphonuclear, leukocytes and eosinophils which engulf and destroy antigens (Kumar *et al*. 2008 and Manmoudi 2008). The major components of innate immunity are epithelial barriers of the skin, gastrointestinal tract and respiratory tract which prevent microbe entry (Kumar *et al.*2008).
- The *adaptive immune* system is triggered when the innate immune system fails to provide protection against an invading pathogen. There are two types of adaptive immune response, the *humoral immunity and cell- mediated immunity* which is mediated by soluble antibody proteins that produces B-lymphocytes (Kumar *et al*. 2008). The function of lymphocytes is to initially recognise a specific antigen. They are divided functionally into B-lymphocytes and T-lymphocytes. T- lymphocytes are responsible for cell mediated immune response while B-lymphocytes are responsible for producing meditating immune response or antibodies (Abbas and Lichtman 2005).

When the immune system is inappropriately triggered or not properly controlled, the same mechanism that is involved in host defence causes tissue injury and disease. The reaction of the cells of innate and adaptive immunity may be manifested as

inflammation due to the release of chemical mediators like histamine and leukotriene (Kumar *et al*., 2008).

2.3 INTRODUCTION TO ALLERGIES

According to Marin and Kipnis (2013), the immune system has the function of protecting the body from foreign pathogens that lead to tissue injury and disease.

An antigen is a toxin or foreign substance which induces an immune response in the body, especially the production of antibodies (Srivastava and Sinha 2008).

An allergy is the response of the body's immune system to substances such as pollens, food and house dust mites, which in most people pose no problem. In allergic individuals, due to their hypersensitive immune system, the allergen triggers the production of Immunoglobulin E (IgE) antibody by activating the B cells. These IgE antibodies bind to the antigen and then to the body's defence cells (basophils, eosinophil and mast cells) which release mediators such as histamine which stimulate the prolonged inflammation, resulting in a wide range of allergic symptoms (Siracusa *et al.* 2011; Kumar *et al.* 2008). Allergic reactions include conditions such as urticaria, allergic rhinitis, angioedema, allergic asthma, anaphylaxis and atopic dermatitis (Anand and Routes 2007).

2.3.1 ALLERGY HYPERSENSITIVITY

According to Oxford Concise colour medical dictionary (2004), a hypersensitive response is prone to abnormal presence of particular antigen, which may cause a variety of tissue reactions. There are four types of hypersensitivity reactions (Kumar *et al.* 2008)

2.3.1.1 Immediate (type 1) hypersensitivity

Activation of helper T cells by environmental antigens leads to the production of IgE antibodies, which releases mediators that transiently affect vascular permeability and induces smooth muscle contraction to stimulate prolonged inflammation.

On the first exposure to an antigen, antibodies specific to that antigen are produced as well memory B cells. On re-exposure, an antibody response is elicited by the antigen. The particular antigens that elicit the immediate hypersensitivity reaction in a genetically susceptible individual produce IgE antibodies and helper T-cells. The helper T-cells become activated and release cytokines, which stimulate the differentiation of the B-cell into plasma cells. IgE circulates to different parts of the body binding to mast cells. The mast cell is triggered to secrete inflammatory mediators, such as histamine. Symptoms of IgE mediated allergen reflect the effects these inflammatory mediators have and the body site in which the antigen IgE-mast cell complex occur (Vander *et al.*2001).

2.3.1.2 Antibody –mediated (type 2) hypersensitivity

This is caused by antibodies that bind to fixed tissue or cell surface antigens that promote phagocytosis and/ or trigger inflammation in the tissue (Kumar *et al.*2008)

2.3.1.3 Immune complex- mediated (type 3) hypersensitivity

This occurs when antibodies bind to antigens to form complexes that deposit in vascular beds and stimulate inflammation which lead to tissue injury (Kumar *et al.*2008)

2.3.1.4 T-cell mediated (type 4) hypersensitivity

This is a cell mediated immune response disorder in which T lymphocytes cause tissue injury, either producing cytokines that induce inflammation and activating macrophages, or directly killing the host cell (Kumar *et al.* 2008).

People suffering from allergies have an imbalanced immune response as seen in the T-helper (Th) cells immune response (Beers *et al.*2006: Underwood 2004). T-lymphocytes are differentiated into three different types of cells the regulatory cells, T helper cells and cytotoxic cells.

T-helper cells release chemical messages that evoke the correct immune response. Th1 are activated in cases of viral or fungal infections, while Th2 are activated by allergens (Manmoudi 2008). An allergic individual`s immune response is already slanted towards Th2 response, caused by genetic and environmental factors, which leads to increased production of IgE producing cells and the development of allergic disorders (Beers *et al.* 2006). Regulatory, Th3, cells secrete anti-inflammatory

substances and have the ability to restore the balance between Th1 and Th2 cells (Abbas and Litchman2005).

A hypersensitive reaction causes conditions such as urticaria, allergic rhinitis, angioedema, asthma and atopic dermatitis (Anand and Routes 2007).

2.4 ALLERGIC RHINITIS

2.4.1 DEFINITION OF ALLERGIC RHINITIS

Allergic rhinitis, commonly known as hay fever, is a hypersensitive reaction towards seasonal and perennial stimuli which cause symptoms such as a blocked nose, itching nose, sneezing and watering of eyes (Greiner and Meltzer 2006). This is an atopic condition indicated by exaggerated Immunoglobulin, IgE, and can occur seasonally or perennially (Beers *et. al*. 2006).

2.4.2 AETIOLOGY

Holloway and Yang (2010), state that allergic disease can be termed as a multifaceted genetic disease involving genetic, environmental and predisposing factors influenced by the development of IgE, Th1, Th2 cells and cytokine meditated mechanisms.

2.4.2.1 Genetic factors

A genetic background in terms of family history of atopic disease has been found as the strongest risk factor for the development of allergic symptoms, irrespective of varying prevalence and environmental risk factors in different societies (Wang 2005).

2.4.2.2 Environmental factors

Due to a rise in the temperature average, as well as increasing in anthropogenic greenhouse gases, there may be an increase in the generation of pollen producing plant species, as well as an increase in the level of pollutants, such as carbon dioxide and nitrogen dioxide, that enhance the allergic response (Higgins and Reh 2012). This theory is further supported by Green *et al.* (2012), that allergic rhinitis is more prevalent in urban areas than rural areas due to high exposure of pollution. Exposure to

bacterial, viral and endotoxins in early childhood increases the intolerance to foreign pathogens (Beers *et al*. 2006).

Other environmental factors contributing include cigarette smoking, diet, house dust, cockroaches, pets, socioeconomic conditions and early introduction to allergenic foods (Wang 2005).

2.4.2.3 Predisposing factors

The predisposing factors are molecules in the bronchial epithelium, skin and gastro-intestinal tract that direct the Th2 cells to attack tissue of allergic reaction (Beers *et al.* 2006).

2.5 TYPES OF ALLERGENS

Allergic rhinitis is due to an immediate hypersensitivity reaction in the nasal mucosa (Colledge *et al.*2010).

Seasonal antigens like pollen from grass, flowers, weeds or trees are responsible for seasonal allergic rhinitis which peak between May and July, a world-wide problem aggravated during harvest season (Colledge *et al.* 2010). South Africa contains indigenous plants that flower from August until April and others prevalent from August until September (Weinberg *et al*. 2008).

Perennial allergic rhinitis is a specific reaction to antigens derived from house dust, fungal spores, moulds or animal dander and symptoms occur all year round (Min 2010). Moulds growing in damp, dark places create spores that are highly allergic and although they are thought to be present all year round, they peak in spring and autumn (Berman 2013). Cockroaches are one of the allergenic factors that occur inland and around coastal areas, such as Kwa-Zulu Natal (Small and Kim 2011).

2.6 CLASSIFICATIONS OF ALLERGIC RHINITIS

As stated by Bousquet *et al.* (2008), allergic rhinitis can be classified into four categories:

2.6.1 Intermittent classification

The affected individual may experience symptoms for less than 4 days per week and for less than 4 weeks.

2.6.2 Persistent classification

Symptoms occurring for more than 4 days/week or lasting more than 4 weeks regardless of the number of days per week.

2.6.3 Mild classification

The affected individual has normal sleep, no impairment of daily activities, sports, leisure, work and no troublesome symptoms.

2.6.4 Moderate classification

The affected individual has one or more of the following items: abnormal sleep, impairment of daily activities, sports, leisure and troublesome symptoms.

2.7 PATHOPHYSIOLOGY

2.7.1 PATHOPHYSIOLOGY OF ALLERGIC RHINITIS

In allergic rhinitis numerous inflammatory cells including mast cells, CD4 positive, T-cells, B-cells, macrophages and eosinophils infiltrate the nasal lining upon the exposure to an inciting allergen. The most common allergens include air borne dust mites, cockroach residues, animal dander, moulds and pollen (Small and Kim 2011).

According to Abbas and Litchman (2006), there are three phases of allergic rhinitis namely *sensitisation phase, immediate phase and late phase*.

As stated by Sin and Togias (2011), on inhalation, the allergen is deposited in the nasal mucosa. After deposition, the antigen presenting cells in the nasal epithelial mucosa phagocytose and process the allergen, subsequently presenting the processed antigen to CD4+ T cells in the lymph-node. The allergen, proliferates in the Th2 cells pathway and releases cytokine; including IL-3, IL-4, IL-5 and IL-13, which leads to local and systemic production of IgE antibodies. The antibodies bind to mast cells and basophils; this process is called the *sensitization phase.*

On re-exposure, the allergen is recognised by IgE antibody that is bound to mast cells and basophils. The recognition and subsequent binding leads to degranulation of mast cells and basophils that release mediators such as histamine, prostaglandin (PGD2) and leukotriene (Shearer and Leung 2010). Histamine produces pruritus, rhinorrhoea and sneezing, while leukotriene and prostaglandin are associated with the development of nasal congestion. This is the immediate *phase* response (Kumar and Clark 2005).

The mediators lead to vasodilation of arteriolar venous anastomosis, plasma leakage from blood vessels, an increased secretion of mucus and stimulation of afferent nerves. *Late phase*reaction is followed by clinical symptoms after 2-6 hours after allergen exposure of early phase reaction (Galli *et al.*2008). Cytokines released commence IgE

antibody production which results in inflammation and chronic allergy (Gould *et al*. 2003).

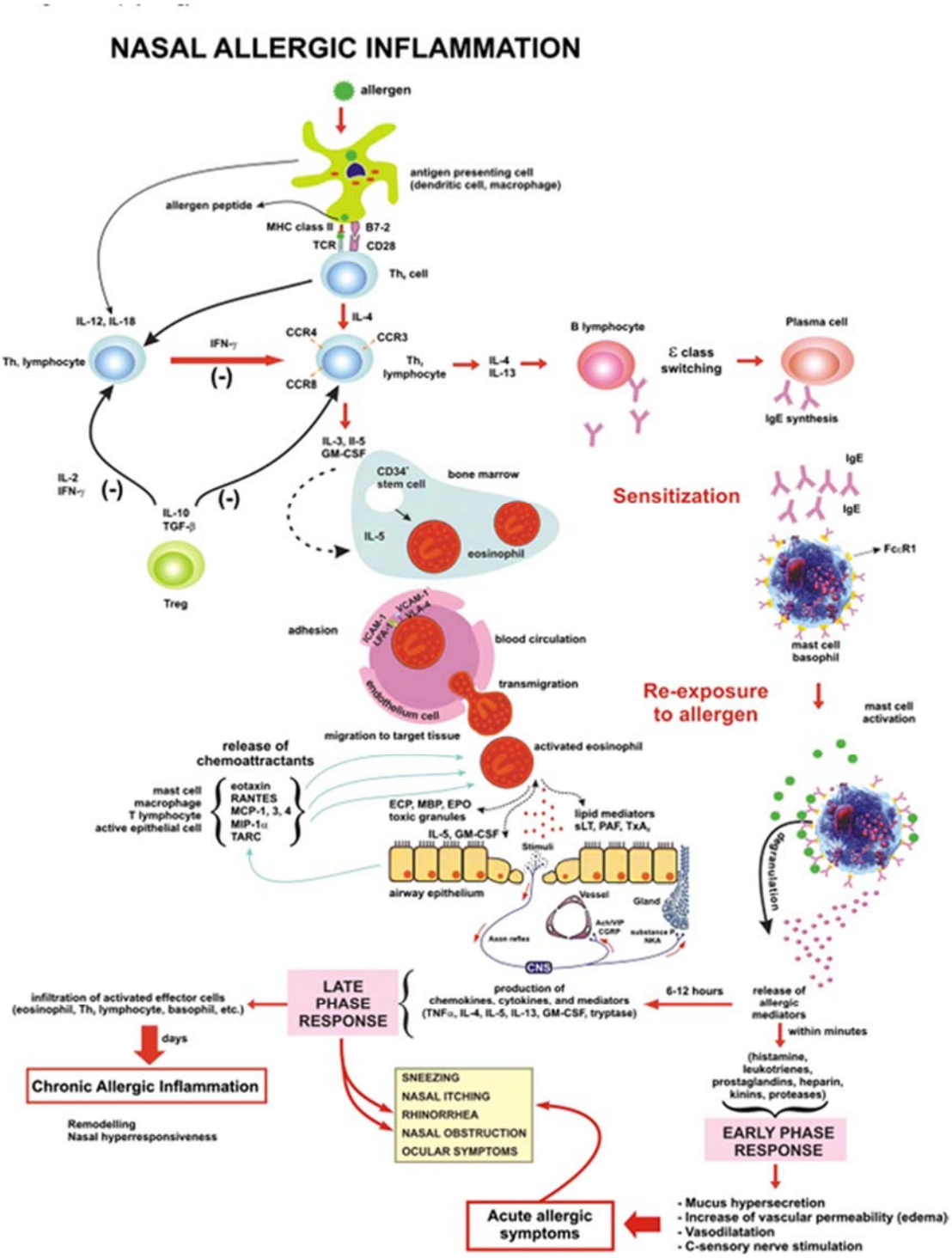

Figure 2-2: Pathogenesis of Allergic Rhinitis (Source: Sin and Togias2011)

2.7.2 NASAL ALLERGIC RHINITIS

According to Sin and Togias (2011) the nasal mucosa is lined by pseudo-stratified squamous ciliated epithelium interspersed with goblet cells and serous, mucous and seromucous glands capable of producing large amounts of mucus that traps large particles from inhaled air. Excessive production of mucus generates rhinorrhoea or a postnasal drip, if drainage occurs towards the nasopharynx. A prominent system of subepithelial capillary beds, venous sinusoids and arteriovenous anastomoses allows for large amounts of blood to pool in the nasal submucosa and rapidly engorge it. These provide a surface for heat and water exchange and support the homeostatic functions of the nose, air conditioning of inhaled air (Bousquet *et al.*2001).

However, excessive blood pooling causes a significant increase in nasal airway resistance and is perceived as nasal congestion or nasal blockage (Sin and Togias 2011). Nasal seromucous glands and blood vessels are highly regulated by parasympathetic and adrenergic innervation deriving from the vidian nerve (Doorly *et al.* 2008). Parasympathetic stimulation through acetylcholine and vasoactive intestinal peptides results in mucus production. Andronergic nerve stimulation through the noradrenaline and neuropeptide has a primarily nasal decongestant effect by constricting blood vessels, reducing blood flow and empting the venous sinusoids (Figueroa *et al. 1998;* Baraniuk *et al. 1992)*. The vascular engorgement is largely the result of reduced sympathetic tone. The parasympathetic and sympathetic control of the nasal glandular apparatus and vasculature is influenced by extrinsic and intrinsic stimuli that results in activation of sensory nerves and generation of central neural reflexes. Nasal sensory fibres are predominantly supplied by the olfactory and trigeminal nerve. These fibres are mostly non-myelinated C fibres and myelinated. A fibre which can sense noxious chemical and physical stimuli (Sarin *et al.*2006). In addition, autonomic central reflexes of the nasal sensory nerves are the site of nasal pruritus and sneezing, both of which are typical allergic rhinitis symptoms.

2.7.3 SENSORY REFLEXES AND RESPONSES

The activation of the sensory nerves during the allergic reaction is the most important element in the generation of acute symptoms of allergic rhinitis, causing stimulation of reflexes that affect the nose via the efferent pathway. Reflexes stimulate the submucosal glands and are responsible for sneezing, itching and hypersecretion of allergic rhinitis. The nasal vasculature is pivotal in the generation of nasal obstruction and it is characterised by the presence of capacitance vessel, under the control of neural and hormonal agents that are capable of expending quickly (Sin and Togias 2011). Nasal hyperactivity may occur due to a hyperactive sensorineural apparatus, inflammation of the nerves in the efferent pathway or glands being altered by allergic inflammation and becoming hypersensitive to the neural stimuli. This creates a setting for irritants, not just allergens, to activate the sensory nerves and increase the inflammatory picture and symptoms of allergic rhinitis as well as to increase the reflex activity and hyper-reactivity of the mucus membrane (Sin andTogias 20011 and Mygind *et al.*1997).

2.8 CLINICAL FEATURES OF ALLERGIC RHINITIS

Allergic rhinitis is characterised by paroxysms of sneezing, rhinorrhoea, and nasal obstruction often accompanied by itching of the nose, eyes and palate. Postnasal drip, cough, irritability and fatigue are other common symptoms (Small and Kim 2011).

Nonspecific symptoms such as tiredness, feeling dizzy, day time lethargy, continuous colds, blinking and eye rubbing, sniffing, snoring and dark circles around the eye may also be experienced (Kemp 2009).

Poorly controlled symptoms of allergic rhinitis may contribute to short term complications such as acute sinusitis; otitis media; sleep disorder breathing; aggravation of underlying asthma and decreased cognitive functioning. Long term complications may include chronic sinusitis, nasal polyps, permanent hearing impairment and sleep apnoea and increased propensity to develop asthma (Sommer 2015). Physical and psychological well-being is also affected which has an impact on the ability to perform daily activities (Sausen *et al.* 2005).

2.9 COMPLICATIONS ASSOCIATED WITH ALLERGIC RHINITIS

Chronic disorders such as eczema, asthma, sinusitis, otitis media, nasal polyps, respiratory infections and orthodontic malocclusion are frequently linked with allergic rhinitis (DiPiro *et al.* 2002; Kemp 2009).

2.9.1 Rhinosinusitis is inflammation of the mucus membrane of the nose and paranasal sinuses (Stedman 2008). Mucosal inflammation leads to ciliary dysfunction, mucus stasis and oedema of the sinus ostia. The stasis of secretion within the sinuses serves as a nidus for bacterial colonization and growth. This growth damages the nasal and paranasal sinuses therefore resulting in sinusitis, pneumonia and influenza (Ahmad and Zacherk 2008).

2.9.2 Nasal polyps are described as the presence of mass tissue, or a grape like structure, bulging from the normal surface level within the nose. Polyps are characterised by a reduction or loss of smell, post nasal drip and facial pain (Bachert and Robillard 2005). A number of studies suggest that a recurrence of polyps is more common in allergic patients than non-allergic patients (Grigoreas *et al.* 2002).

2.9.3 Asthma is chronic inflammation of the airways that causes recurrent episodes of wheezing, breathlessness, coughing and chest tightness, particularly at night or in the early hours in the morning (Kumar *et al.* 2008). Nasal allergy shows challenge in seasonal allergic rhinitis patients, where there is an increase of bronchial hyper-responsiveness or bronchospasm during immediate and late phase reaction (Kim *et al*. 2008). Medications that are effective in treating AR can ameliorate asthma symptoms (Fireman 2000).

2.9.4 Sleep disorder breathing, such as apnoea and hypopnoea increase as a result of nasal congestion and thus result in limiting nasal air flow (Nathan 2008). Mullol *et al.* (2008) reported that the middle aged population with nasal obstruction are more likely to be habitual snorers.

2.9.5 Shedden (2005) conducted an online survey to assess the quality of life in 2002 patients with allergic rhinitis, 59% reported that their congestion had affected their work

performance and 42% caregivers reported that allergic rhinitis had a bad impact on child performance in school. Nasal congestion associated with allergic rhinitis lead to feelings of discomfort, frustration, fatigue, irritability and stress (Canonica *et al.*2008).

2.10 DIAGNOSIS OF ALLERGIC RHINITIS

2.10.1 Case history taking

The history will include the patient's chief concern and symptoms and often includes the pattern, chronicity, seasonality and triggers of nasal symptoms and its related symptoms; family history; current medications; response to previous treatment modalities; presence of co-existing conditions; occupational exposure and detailed environmental history (Wallace *et al.*2008).

2.10.2 Physical examination

The physical examination of all organ systems potentially affected by allergies should be performed in all patients with a history of rhinitis. Emphasis should be on the upper respiratory tract but the patient should also be examined for the presence of accompanying otitis or Eustachian tube dysfunction, chronic sinusitis, nasal polyps, conjunctivitis, asthma and atopic dermatitis (Dykewicz and Hamilos 2010). Examination of the nose reveals swelling of the nasal mucosa and palate. An internal endoscopic examination of the nose should also be considered to assess for structural abnormalities and nasal polyps (Small *et al.*2007).

2.10.3 Diagnostic blood tests

Diagnosis entails allergy testing such as skin prick testing, total serum IgE, Phadiatop® inhalant screen and radio-allergosorbet test (RAST) (Morris 2006).

2.10.3.1 Testing for IgE

Determination of specific IgE, preferably by skin testing is indicated to provide evidence of an allergic basis for the patient's symptoms, or to assess the sensitivity to a specific allergen. This can then be used for avoidance measures and allergen immunotherapy (Hamilton and Adkison 2003; Dolen 2001). Allergy tests should always be interpreted in the context of the patient's clinical presentation, age, relevant allergy exposure and the performance characteristics of the allergy test (Cox *et al.* 2008).

2.10.3.2 Radio-Allergo-Sorbent test (RAST)

The RAST test is a radioimmunoassay-based procedure to detect IgE bound allergens responsible for tissue hypersensitivity. It is a most useful test to perform when the skin prick test cannot be performed such as in children, generalised dermatitis or where if there is a risk of anaphylaxis, or when a person is taking antihistamine medication which may interfere with accurate skin prick testing (Wallach 2007; Smith 2013).

2.10.3.3 Phadiatop® inhalant screen

Phadiatop® is a test that is capable of detecting the presence of IgE specific to the inhalant allergens that are most common in the tested *environment* simultaneously (Yungingere*t al.*2000). This test is not affected by any variable such as age, race or parasites. It gives a 'yes' or 'no' results with 96% sensitivity and 94% specificity (Morris 2006 and LabSpec 2007).

2.10.3.4 Multiple Allergens Simultaneous Test (MAST)

This test uses photo reagent and is able to identify multiple allergens simultaneously. The test is not influenced by drug use, is less invasive and can be used by patients with generalized dermatitis. However, MAST has low sensitivity as compared to RAST (Min 2010).

2.11 MANAGEMENT AND CONVENTIONAL TREATMENT OF ALLERGIC RHINITIS

The treatment goal for allergic rhinitis is the relief of symptoms. Therapeutic actions available are avoidance measures, antihistamine, intranasal corticosteroids, allergen immunotherapy, decongestants, oral corticosteroids and leukotriene receptors antagonists (Small and Kim 2011).

2.11.1 Avoidance measures

The avoidance of allergens by means of controlling the environment and exposure to allergens, should be considered as the primary treatment. These can improve patients' symptoms, reduce the need for pharmacotherapy and reduce the progression of allergic rhinitis to asthma (Scadding and Fokkens 2007 and Butler 2009).

2.11.2 Antihistamine

These agents have been found to effectively reduce sneezing, itching and rhinorrhoea when taken regularly at the time of maximal symptoms, or before exposure to an allergen. Sedating antihistamines such as diphenhydramine or chlorpheniramine are effective in relieving symptoms; however, they have shown to negatively impact cognition and functioning and are therefore not recommended for the treatment of allergic rhinitis (Kim *et al.* 2008 and Small *et al.* 2007).

2.11.3 Intranasal corticosteroids

Intranasal corticosteroids are the first line of therapeutic options for patients with mild persistent or moderate symptoms and they can be used alone or in combination with oral antihistamine or leukotriene. When used regularly and correctly, intranasal corticosteroids effectively reduce inflammation of the nasal mucosa and improve mucosal pathology. Although side effects are typically minimal with the use of intranasal corticosteroids they can cause nasal irritation and bleeding (Butler 2009; Small and Kim 2011).

2.11.4 Oral and intranasal decongestant

Oral and intranasal decongestants like pseudoephedrine or phylephrine are useful in relieving nasal congestion, however the side effects include agitation, insomnia, headaches and palpitations. These agents are contraindicated in patients with uncontrolled hypertension and severe coronary heart disease. Prolonged use of an intranasal decongestant carries the risk of rhinitis rebound congestion (Kim *et al.*2008 and Lee *et al.* 2004).

2.11.5 Antileukotrienes

Anti-leukotrienes are lipid mediators used in the relief of allergic rhinitis. They are used to reduce nasal congestion and improve quality of sleep. However, they have been found less effective in improving nasal and throat itching (Greiner and Meltzer 2006).

2.11.6 Intranasal Cromolyn sodium

It is used to treat allergic rhinitis by inhibiting degranulation of mast cells and inhibiting the release of inflammatory mediators (Wallace *et al.*2008). Cromolyn sodium does not treat symptoms but rather prevents the onset of subsequent symptoms, therefore

it is best to use when a patient has previous knowledge of a contracted allergen (Manmoudi 2008). The side effects of Cromolyn sodium are sneezing, irritation of nasal mucosa and an unpleasant taste (Greiner and Meltzer 2006).

2.11.7 Intranasal ipratropium bromide

Intranasal ipratropium bromide is an anti-muscarinic agent that has been shown to be effective when watery secretion is present but less effective with mucoid secretions (Manmoudi 2008). Side effects include local irritation, dryness and epistaxis (Greiner and Meltzer 2006).

2.11.8 Allergen immunotherapy

According to Kim, Bouchard and Renzi (2008) and Butler (2009), allergen immunotherapy involves subcutaneous administration of gradually increasing quantities of the patient relevant antigens until a dose is reached that is effective in inducing immunologic tolerance to the allergen. This form of therapy is shown to be effective for the treatment of allergic rhinitis caused by pollen and dust mites, but it carries the risk of anaphylactic reaction.

2.12 ALTERNATIVE TREATMENT FOR ALLERGIC RHINITIS

2.12.1 Acupuncture

Acupuncture is part of Traditional Chinese Medicine and is widely used for the treatment of chronic illness, including asthma. The theory behind the use of acupuncture is to restore the balance of the “vital flows” by inserting needles at exact points of the body surface, where the “meridians” of the flow lie (Vickers *et al.* 2002).

A controlled clinical trial in children with perennial allergic rhinitis reported a significant improvement in daily symptoms and an increase of symptom-free state in the active group with no change in the use of symptomatic medication (Taw *et al.*2015).

2.12.2 Phytotherapy

Phytotherapy is an herbal treatment that contains several active pharmacological ingredients that have measurable clinical effect (Barrett *et al.*1999). A randomised

double blind clinical trial using *Arthospira platensis,* has shown to promote interferon gamma production and natural killer cell to reduce IL-4 level by 32% (p=0.0082) in treatment of allergic rhinitis this has dramatically improved allergic symptoms (Hirahashi *et al.* 2002).

A study on seasonal rhinitis found that a mixture of 18 Chinese herbs was significantly better than placebo in terms of symptoms and quality of life (Xue *et al.*2003). *Butterbar* is a plant extract that has been proved in several randomised double blind studies to be as effective as pharmaceutical drugs and superior to placebo in relieving nasal symptoms due to allergic rhinitis (Bernstein *et al.* 2002 and Lee *et al.* 2004).

2.12.3 Sublingual immunotherapy

Sublingual immunotherapy is an allergen specific form of immunotherapy whereby treatment containing an allergen solution is given orally to the individual. This medication over the course of treatment, reduces sensitivity to allergens (Frew 2010). Sublingual immunotherapy has a good safety profile for adults and children and it can be taken at home. This form of treatment is costly and requires years of treatment in order to be effective (Wise *et al.* 2009).

2.12.4 Nasal saline

There is evidence that topical saline is beneficial in the treatment of symptoms of chronic rhinorrhoea and rhinosinusitis when used as a sole modality or for adjunctive treatment (Wallace *et al.*2008). Hot wet compresses are applied over the inflamed area to alleviate symptoms of congestion (Li *et al.* 2013).

2.12.5 Diet

Food that commonly cause or increase nasal congestion should be avoided, these include cow's milk and gluten (Balch *et al.*2016). Complementary medicine, vitamins, minerals and supplements are amongst the most common resources to fight against allergens (Dixon and Ernst, 2001). Probiotics and food rich in omega 3 and fatty acid such as fish, almonds, walnut, pumpkin and flax seed help to reduce allergic rhinitis symptoms (Vliagoftis *et al.* 2008).

2.13 HOMOEOPATHY

Homoeopathy is based on the fundamental principle of *"like cures like"* meaning that any substance which can produce a totality of symptoms in a healthy human being can cure the totality of symptoms (Vithoulkas 2002 and Ahmad 2005).

Homoeopathic medicine helps to hasten recovery by stimulating the Vital Force, a subtle energy within the body that responds to the tiny provocations of the medicine, and enables the body to heal itself. The medicine helps the body to return to its healthy state by energizing the vital force to eradicate the disease (Lockie and Geddes 2001).

2.13.1 Polypharmacy

Polypharmacy is the method of homoeopathic prescribing when more than one medicine is prescribed simultaneously on the basis that they all have a degree of similarity to the particular disease process (Watson 2004). A combination of medicine "complex" is usually prescribed so as to treat more than one symptom of the same condition (Kayne 1997).

According to Reckeweg (2002), complex medicines have a better effect than the use of a single remedy because:

- they have a faster action,
- they cause minimal initial aggravation,
- they can be used for acute as well as chronic disorders,
- it acts on organic functional and mental level

2.13.2 Potency

Potency is the term used to indicate the strength of the homoeopathic remedy. Potentization is a process of serial dilutions and succussion peculiar to homoeopathy. A combination of a number and letter indicates the potency of the remedy; the number indicates the number of succussion and dilutions that have been carried out. The letter refers to the proportion of the dilution, C (centesimal) stands for 1 in 99 dilutions while D (decimal) denotes 1 in 9 dilutions. For each stage of dilution and succussion one

part of the previous dilution is added to 99 parts of water or alcohol and this will result into C potency and one in nine will result in a D potency (Lockie and Geddes 2001).

According to the Homoeopathy Plus (1997-2014), the potency of the medicine is selected according to the sensitivity of the symptoms as well as the level at which symptoms occur:

1. If the homoeopathic relationship of the medicine corresponds to the level of the local symptoms, then low dilution of medicine is utilized *ie.* 1CH- 15CH
2. If the correspondence is at the level of general symptoms and modalities, then the medium solution is utilized *ie.*30-200CH
3. If the correspondence is at the level of nervous symptoms, then high dilutions of 200CH to M are utilized

2.13.3 Aggravation

Homoeopathic aggravation is a temporary worsening of existing symptoms following the administration of a correctly chosen homoeopathic prescription, which is expected to be followed by an improvement (Vithoulkas 2002). Hahnemann postulates that the medication must be naturally stronger than the ailments and homoeopathic aggravation is a good prognosis that the acute symptom will yield from the first dose (Hahnemann 2011).

2.14 SIMILISAN NASAL ALLERGY RELIEF SPRAY®

It is a commercially available homoeopathic nasal spray. According to Similasan Corporation (1999-2015) the nasal spray is 100% natural and contains active ingredients with non-drowsy effects which relieves allergic congestion, itching and runny nose and it is a preservative free nasal mist. *Similasan Nasal Allergy Relief Spray*® mist gently stimulates the body's natural ability to relieve allergic congestion, itchy, runny nose and rhinitis caused by pollen, pet dander, dust and mould spores.

The *Similasan Nasal Allergy Relief Spra*y® mists are not habit forming and will not cause reliance or a rebound effect. The ingredients are *Cardiospernum halicacabum 6X, Galphimiaglauca 6X, Luffa operculata 6X, Sabadilla officinarum 6X* (Similasan Corporation 1999-2015).

Summary of ingredients in the *Similasan Nasal Allergy Relief Spray®:*

2.14.1 Cardiospernum halicacabum *6X*: the plant belongs to the *Sapindaceae* family. As an herb it is used as diuretic, laxative and anti-inflammatory (Kumaran and Karunakaran 2006 and Rao *et al.*2006). Cardiospernum as a homoeopathic remedy is suitable for the treatment of inflammatory and pruritic skin diseases. It is indicated for itchy; copious nasal discharge, sometimes clear or thick and yellow mucus; sneezing and pain on the frontal sinuses. Eye: increased lacrimation; irritability and itchy sensation in the eyes; dryness of the eye; burning pain worse at night (Riley 2012).

2.14.2 Galphimiaglauca *6X*: commonly known as *Thryallis* belongs to the *Malpighiaceae* family. The dried leaves and flower of the plant are used to make the remedy (Reckeweg 2002). Homoeopathically the plant is designated for allergic vasomotor action in the nose with burning discharge from eye and nose (Reckeweg 2002). It is useful for heaviness of the lids and itching of the eye in the morning; sore pain around the eye; redness of the eyelid or conjunctiva and has a sensation of scratching around the eye. Sneezing that is constant or in the morning; internal dryness. Coryza with excoriating discharge that is worse during motion (Riley 2012).

2.14.3 Luffa operculata *6X:* this plant is part of the *Cucurbitaceae f*amily and is native to South America. In its herbal form it is used as a purgative, emetic, anti-asthmatic and diuretic. It is also indicated for a reduced sense of smell, catarrh and rhinitis (Reckeweg 2002). Homoeopathically it is indicated for frontal headache that is better in the evening and worse in stuffy room and eyes tearful with sensitivity to light. The nose is obstructed with frequent sneezing and watery discharge which gets worse in dust and cold and better in heat. It is also indicated for chronic rhinitis with involvement of sinusitis, chest pain and coughing as well as dry inflamed throat (Juneja 2005).

2.14.4 Sabadilla officinarum *6X: T*his Mexican genus plant belongs to the Colchium family of the *Liliaceae,* commonly known as Cevadilla seeds (Herb200.com, 2002-

2017). A tincture of the remedy is made from seeds and it acts on the mucous membrane of the nose and lacrimal glands to produce hay-fever like symptoms (Varma and Vaid 1997). According to Vermeulen (2001), the eyes red burning; lacrimation worse during sneezing, coughing on open air. Nose is oversensitive to odours; spasmodic sneezing and running nose: itching, tickling in the nose.

2.15 OTHER RELATED LITERATURE

According to Ullman and Frass (2010), respiratory allergies are best treated by prescribing the individual selected homoeopathic constitutional medicine according to the specific and unique genetic history, personal health and total presence of physical and psychological symptoms experienced.

Goossens *et al*. (2009) studied the quality of life after individualised homoeopathic treatment for seasonal AR and revealed that 52% of participants improved and showed alleviation of their symptoms of allergic rhinitis.

The one drawback to individualised treatment is the time taken for consultation. This is why a complex that is sold commercially is being investigated.

Other homoeopathic complexes have also been investigated with regards to the treatment of allergic rhinitis. Arthur (2009) studied the effect of *Luffeel*® homoeopathic nasal spray and tablets on allergic rhinitis and found a reduction in symptoms when compared to the placebo group with no rebound or lethargic effect.

Trompetter, Lebert and Weib (2015) investigated the efficacy of a homoeopathic complex, *Gelsenium sempervirens, Alumen chromicum* and *Acidum formicicum, in* the treatment of adults and children who had been suffering from allergic symptoms for more than two years. At least 82.2% of participants in the study showed a reduction in the severity of the symptoms from moderate to mild or not present at all. The quality of life improved, symptoms reduced and a good tolerability to the treatment without side effect.

Naidoo and Pellow (2013) conducted a randomized placebo controlled study of Cat saliva 9CH and Histaminum 9CH in cat allergic dust. Skin prick test (SPT) was used

as the measuring tool, the results for cat allergen showed highly statistical significant reduction in the experimental group. Participants went from having a positive SPT for cat allergy at the beginning of the study to no reaction to the same allergen. This shows that homoeopathic complex Cat saliva 9CH and Histaminum 9CH reduce the sensitivity of cat allergy.

2.16 CONCLUSION

There is evidence supporting the fact that homoeopathy can be successful in alleviating symptoms of allergic rhinitis and therefore increasing the patient's quality of life (Naidoo and Pellow 2013; Trompetter, Lebert and Weib 2015; Arthur 2009; Danks, Es and Poter 2004; Taylor *et al.*2000). Homoeopathic medications are safe and effective without causing any side effects as seen in allopathic medication (Bornhoft *et al.* 2006; Weiser, Gegenheimer and Klein.1999). There is no suppression of symptoms but effective relief in patients with allergic rhinitis (Heel Inc, 2004).

Homoeopathy appears to offer possible options to conventional treatment of respiratory allergies. A homoeopathic dose of a specific allergen or individual selected homoeopathy constitutional medicine have shown to be effective in treatment and there is evidence to support that homoeopathic treatment and placebo are different (Ullman and Frass 2010). This is why this commercially available product has been tested to add to the collection of adjunctive therapies available to patients suffering from allergic rhinitis.

CHAPTER 3 - METHODOLOGY

3.1 RESEARCH METHODOLOGY

Statistics has two broad categories namely, descriptive and inferential. As explained by Lind, Mason and Marchal (2002), descriptive statistics describe, organise and summarise a particular set of quantitative data. Although such statistics makes no inference or predictions, they are however, useful in summarising results for an experiment. Both Univariate and Bivariate descriptive statistical procedures were used to analyse the data in this study. Salkied (2007) and Field (2009) pointed out that Univariate and Bivariate is most appropriate for descriptive statistics. Bar graphs and tables were used to present data. Non-parametric test using One-sample Kolmogorov-Smirnov (KS) test was used to determine the normal distribution of CARAT questionnaire. Cunningham and Aldrich (2012) asserted that the purpose of KS is to determine if the distribution of values approximates the normal curve. In addition, Pearson Chi-square was used to analyse the scoring pattern of the respondents.

With reference to the inferential statistical analysis, Johnson and Christensen (2012) elaborated that inferential statistics, by contrast, uses the laws of probability to make inferences and draw statistical conclusions about the sample data. Barnes (2011) indicated that the independent t-test is the most appropriate parametric test to identify the mean difference between two variables. The independent t-test was used to analyse the CARAT scores between the treatment and placebo group, with $p < 0.05$ set as statistically significant. More so, paired sample t-test and ANOVA were used to compare the intra and inter group relation at different visits to the clinic for both the treatment and placebo group. All analyses were performed using SPSS (Version 24®).

3.1.1 STUDY DESIGN

This was a randomised double blind clinical study, which included a quantitative method of analysis.

3.1.2 SETTING

The study was conducted at the Durban University of Technology (DUT), Homoeopathic Day Clinic (HDC) under the supervision of a qualified and registered Homoeopath.

3.1.3 POPULATION

Individuals between the ages of 18 -50 years who met the Inclusion Criteria (Appendix C) were included in the study.

3.1.4 INCLUSION CRITERIA

Participants met the inclusion criteria for AR (See Appendix C):

- Participants were between 18 -50 years of age.
- Participants were English or IsiZulu literate.
- Participants lived around Durban – KwaZulu-Natal (for easy access to the site of study).
- Participants were willing to follow the study requirements.

3.1.5 EXCLUSION CRITERIA

- Participants who did not meet the inclusion criteria for AR.
- Participants who were on recreational drugs.
- Participants who took AR treatment (corticosteroid or decongestions) within the 4 weeks that preceded
- Participants who had a co-existing chronic medical condition (asthma, fever or anatomical nasal disorder.
- Participants who were pregnant, nursing or intending to conceive during the time of the study.
- Participants who had had surgery in the past six weeks.
- Participants who were not willing to maintain their normal lifestyle during the study.
- Participants who were illiterate.

3.1.6 RECRUITMENT

Participants were recruited through advertisements (Appendix I) that were placed on DUT noticeboards, other tertiary institutions, health shops, shopping malls, public clinics, hospitals, libraries and churches. Participation was voluntary and there was no coercion to participate.

3.1.7 SAMPLE SIZE

Based on previous Homoeopathic clinical trial studies done at DUT by Jones (2009), Ismail (2003), Ebrahim (2003), and Dlamini (2003) among a few, which have used 30 participants in their trial, a sample size of 30 was deemed statistically significant. Therefore, a sample size of a minimum of 30 contesting participants was evenly distributed between the randomisation list. Randomisation was done by an independent person at the DUT Homoeopathic Day Clinic. The Randomisation list was being kept at the clinic where the research student had no access to it until the study was completed and when the un-blinding was done.

3.1.8 RANDOMISATION

Randomisation was done by an independent person at the Durban University of Technology Department of Homoeopathy. Participants were evenly distributed to the treatment and placebo group according to the randomisation list. The randomisation list was kept at the clinic, the researcher nor supervisor had access to it until the study had been completed.

This was a double blind study. Neither the researcher nor the supervisor knew whether the patient was getting active ingredient or placebo until the end of the study when were the study was unblended. There were no withdrawals or dropouts from the study.

3.2 CARAT MEASUREMENT TOOLS

Control of Allergic Rhinitis and Asthma Test (CARAT10) (Appendix D)

According to Azevedo*et al.* (2013) and Fonseca*et al.* (2012) CARAT10 has good test-retest reliability, responsiveness and longitudinal validity. It can be used to assess control of allergic rhinitis and asthma, both to compare groups in clinical studies and to evaluate individual patients in clinical practice.

The CARAT questionnaire is self-administered and is composed of 10 questions; each question with 4 possible answers (scale 0–3) and the total score varies from 0 to 30. These ten questions address upper and lower airways symptoms, sleep interference, activity limitation and the need to increase medication over a four-week period.

A CARAT total ≤24 means poor disease control. The first four questions evaluate rhinitis (CARATr) and the last six questions evaluate asthma (CARATa). Scores CARATr ≤8 and CARATa<16 mean poorly controlled rhinitis and asthma, respectively.

3.3 DAILY LOG RECORDS

This was a book in which participants had kept as a daily record of events and experiences using their individual symptoms of allergic rhinitis. The daily record was used to determine the quality of life elements and frequency in administration of the *Similasan Nasal Allergy Relief Spra*y®.

According to Demoly*et al.* (2013), the self-assessment score of allergic rhinitis appears to change and correlate the clinical expression of rhinitis and also involvement with the treatment. The results suggest that completion of a daily questionnaire could help to determine the standardised level of control of allergic rhinitis of an individual patient.

3.4 MANUFACTURING PROCESS OF SIMILISAN NASAL ALLERGY RELIEF SPRAY®

Similasan Nasal Allergy Relief Spray® is a commercially available homoeopathic nasal spray. The ingredients are: *Cardiospermum 6X, Galphimiaglauca 6X, Luffa operculata 6X, Sabadilla 6X.*

The *Similasan Nasal Allergy Relief Spray*® is a homoeopathic product manufactured by Similasan Corporation USA (Appendix J). *Similasan* prepared the remedy and the placebo was prepared using a concentrated 0.09% sodium chloride in water from pharmacology laboratory in Durban University of Technology. Both the verum and the placebo were dispensed in identical nasal spray bottles to maintain blinding. The medication was delivered by *Similasan* to the Homoeopathic Day Clinic Dispensary (HDCD) and it was stored in the dispensary laminar flow room.

3.5 MANUFACTURING OF PLACEBO MEDICATION

The placebo medication was prepared from a saline solution, which is a mixture of sterile water and water, a mixture of sodium chloride in water in 0.09% concentration. The medication was stored in the dispensary laminar flow room Homoeopathic Day Clinic Dispensary (HDCD).

Only the dispenser knew whether the medication dispensed is active or placebo.

3.6 INSTRUMENT

Control of Allergic Rhinitis and Asthma Test (CARAT10) (Appendix D) was applied by the researcher at the beginning of each consultation and Daily log records (Appendix C) was given to the participant to complete for the duration of 4 weeks of the study.

3.7 PROCEDURE

The duration of the study took place for a period of four weeks. There were two consultations in which the measurement tools were applied.

The first consultation was regarded as the baseline, thereafter the participant was seen for the second consultation which was a follow up after 3 weeks of treatment. The participants were given treatment according to the randomisation list.

3.7.1 Consultation one:

- Step one: The participant was fully informed about the study. The participant was given an information letter (Appendix A), the participant had an opportunity to ask questions about the study.
- Step two: The participant signed the consent form (Appendix B) on agreeing to participate in the study.
- Step three: On both the information letter and consent form there was information about participants not being forced to participate in the study and that there was no remuneration for taking part in the study. Participants were free to withdraw at any time during the study without any prejudice.
- Step four: If participants met the inclusion criteria (Appendix C), the researcher applied the measurement tools (Appendix D).
- Step five: A detailed case history was taken (Appendix K)
- Step six: A full physical examination was performed and a SOAPE note was completed by the researcher and signed by the clinician on duty (Appendix L).
- Step Seven: Medication was dispensed according to the randomisation list drawn up by an independent person (one group had an active nasal homoeopathic complex spray and the other had an inactive nasal spray.
- Step eight: The participant then proceeded to the Clinic reception area where the dispenser or clinician on duty dispensed fully labelled allocated medication with instructions on when and how to take the medication (Appendix M).

3.7.2 Consultation two:

- Step nine: The researcher called the participant and reminded them of their next consultation- 3 weeks after their initial consultation.
- Step ten: The researcher applied the measurement tools (Appendix D)
- Step eleven: A detailed follow up case was taken (Appendix N)
- Step twelve: A full physical examination was performed and a SOAPE note was completed (Appendix L). There was no medication prescribed on this final follow up.

The participants were thanked for their participation in the study and they were informed that they are welcome for further treatment at the HDC should they need to and those in the placebo group were given free treatment at the end of the research.

3.8 POSOLOGY AND DOSAGE:

- Both the treatment and placebo was dispensed in a 20ml plastic seal nasal spray bottle.
- A standardised second spray was given at any time, if first medication was finished before the end of the study.
- Participants must remove plastic seal from the bottle.
- Participants must lift the cap off the bottle.
- Participants must spray 1-3 times into each nostril.
- Participants may use as needed.
- Participants must replace the cap after use.

3.9 PLACEBO

In clinical studies, a placebo is commonly used. According to the Oxford English Dictionary (2004) a placebo is an inert or innocuous substance used especially in controlled experiments testing the efficacy of another substance. Research has shown that the expectations of patients can influence their healing process and since they expect their medication to work, the placebo may have therapeutic effect. Therefore, during a clinical study, active medication is tested against a control receiving a placebo to make sure that any positive results take into account this placebo response, and for any medication or drug to be deemed effective the positive results shown by the treatment group must far outweigh the placebo group (Moerman 2002).

In this clinical study, a saline solution was used to maintain the integrity and similarity between the two products, the only difference is the remedies an active. This was done to keep continuity, so that the patient will not be able to identify whether they given placebo or treatment.

3.10 ETHICS AND CONFIDENTIALITY

The study was carried out according to the approved DUT protocol and standards (Appendix O). After participants were informed of all the known possible risks involved, full permission was attained from the participant. The participants were participating in this study voluntarily and there was no coercion by the researcher or the supervisors. The study was always under constant supervision by the supervisors and the clinicians on duty at the HDC. Permission to use all the scales was granted by the respective people.

All data collected from participants was handled with strict confidence. Only the supervisors, the researcher and the clinic receptionist have access to the participant's file. Participant's particulars not relevant to the study were not mentioned in public, and all data was coded in numbers and password protected. The data collected s stored in a safe place with the department of homoeopathy and will be destroyed appropriately after 5 years as per DUT regulations.

Prior to commencement of the study, letters requesting permission to use DUT facility (Homoeopathic Day Clinic and dispensary), students and staff was sent to the relevant people (Appendix F) and Professor Sibusiso Moyo, the Research and Postgraduate Support Director. Once permission was granted the study commenced.

3.11 DATA ANALYSIS

As illustrated by Shier (2004), Independent t- test is parametric test that allows two groups to be compared without making assumption that values are normally distributed. ANOVA test is a parametric statistical hypothesis test used to compare two related sample to assess whether their population mean ranks differ (Rosner*et al.* 2006). These two tests were used to compare the mean differences within the two groups.

CHAPTER 4 - RESULTS AND INTERPRETATION

4.1.1 INTRODUCTION

This chapter presents the outcome of the data gathering process, reports the results, and discusses the findings obtained from the questionnaire. In this section, the questionnaire was the primary tool that was used to collect data and was distributed to out-patients attending the Homoeopathic Clinic, Durban University of Technology, South Africa. The data collected from the responses was analysed with SPSS (version 24®) in relation to the two objectives outlined in Chapter One, that is: (1) to determine the efficacy of a homoeopathic *Similasan Nasal Allergy Relief Spray*® in the management of allergic rhinitis in terms of the CARAT questionnaire, (2) To determine the efficacy of a *Similasan Nasal Allergy Relief Spray*® in the management of allergic rhinitis in terms of the terms of the daily log records using individual symptoms of allergic rhinitis over 4 weeks of intervention.

All the data in the sections below were statistically analysed in an attempt to determine the efficacy of homoeopathic *Similasan Nasal Allergy Relief Spray*® in the management of allergic rhinitis in terms of CARAT. The results were presented in descriptive statistics in the form of graphs, cross tabulations and other figures for the quantitative data that was collected. Inferential techniques include the use of correlations and chi square test values; which are interpreted using the p-values.

4.1.2 The Sample

In total, 33 questionnaires were completed and, 3 were discarded as the sample size was attained. It is worth mentioning that questionnaires which were not sufficiently completed were disregarded. More so, Shu *et al.* (2004) argues that an above 60 per cent response rate is suitable for a study. Hence, it can therefore be inferred that the response rate of 100% is sufficient for this study.

4.1.3 The Research Instrument

The research instrument consisted of 28 items, with a level of measurement at a nominal or an ordinal level. The questionnaire was divided into two questions which measured various themes as illustrated below:

1. Inclusion criteria for allergic rhinitis
2. Control of Allergic Rhinitis and Asthma Test (CARAT)

4.2. RELIABILITY: RESEARCH INSTRUMENTS

Before discussing the findings of this study, this section deliberately focuses on a few issues of reliability. Reliability is computed by taking several measurements on the same subjects (Barnes 2011). A reliability coefficient of 0.70 or higher is considered as “acceptable”. The table below reflects the Cronbach’s alpha score for all the items that constituted the questionnaire.

As shown in Table 4-1, each group on its own showed larger variations in the scoring patterns which resulted in lower than normal Cronbach alpha scores. A similar inconsistent scoring pattern was also measured for the combined group.

Table 4-1: Survey scales and Predictor variables in CARAT Analysis

Survey scales	Predictor variables	Number of Items	Cronbach's Alpha score
1	Treatment	24	0.539
2	Placebo	24	0.570
3	Combined	24	0.539

4.3. BIOGRAPHICAL AND DATA RESPONSES

This section summarises the biographical characteristics of the respondents. Respondents are described in terms of their age distribution. As shown in Figure 4-1, the placebo group had the majority of the respondents within the age category 18-26 years (71%), as well as 41-50 years (11%). The treatment group were however, the majority for the respondents within the age group 27-34 years (30%).

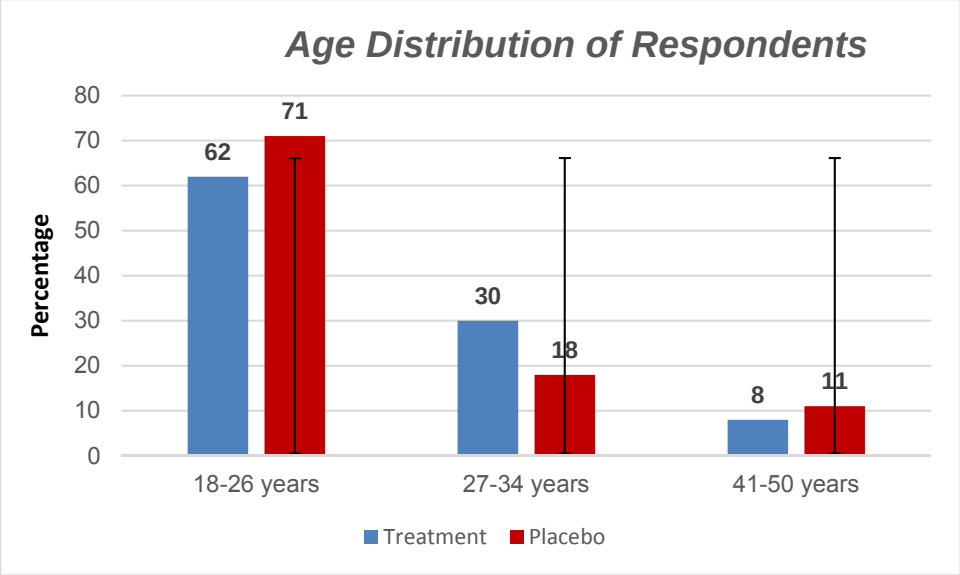

Figure 4-1: Demography of respondents showing age distribution for both treatment and placebo group.

4.3.1 Section Analysis

The section that follows analyses the scoring patterns of the respondents per variable per section. The results are first presented using summarised percentages for the variables that constitute each section. Results are then further analysed according to the importance of the statements. The traditional approach to reporting a result requires a statement of statistical significance. A p-value is generated from a test statistic. A significant result is indicated with "$p < 0.05$".

The Pearson Chi-square tests for individual patients scoring pattern on the CARAT baseline is summarised in Figure 4-2. As indicated by the level of significance, it was noted that there was no statistically significant difference between the treatment and the placebo for the entire scoring pattern (p>0.05). More so, and with regards to the CARAT first and second visit, it was also observed that the Pearson Chi-square revealed no significant differences between the treatment and placebo group for both CARAT first and second visit, respectively (Appendix N).

Table 4-2: Responding scoring pattern for CARAT baseline

		Almost every day	More than 2 days a week	1 or 2 a week	Never	Pearson Chi-square Test
Blood nose	Treatment	30.0	10	6.7	3.3	0.467
	Placebo	16.7	6.7	16.7	0.0	
Sneezing	Treatment	30.0	3.3	16.7	0.0	0.178
	Placebo	16.7	16.7	13.3	3.3	
Cough	Treatment	0.0	3.3	3.3	36.7	0.258
	Placebo	10.0	3.3	13.3	23.3	
Runny nose	Treatment	26.7	10.0	10.0	3.3	0.519
	Placebo	23.3	6.7	20.0	0.0	
Shortness of breath/dyspnoea	Treatment	0.0	0.0	3.3	46.7	0.368
	Placebo	3.3	0.0	0.0	46.7	
Wheezing in the chest	Treatment	0.0	0.0	0.0	50.0	
	Placebo	0.0	0.0	0.0	50.0	
Chest tightness upon physical excision	Treatment	0.0	0.0	0.0	50.0	
	Placebo	0.0	0.0	0.0	50.0	
Tiredness due to your allergic rhinitis	Treatment	33.3	13.3	3.3	0.0	0.182
	Placebo	23.3	6.7	16.7	3.3	
Wake up during the night because of your allergic rhinitis symptoms	Treatment	26.7	16.7	3.3	3.3	0.162
	Placebo	20.0	6.7	20.0	3.3	
	Treatment	0.0	0.0	0.0	15.0	

In the last 4 weeks how many times did you have to increase the dose or frequency of medication due to your allergic rhinitis	Placebo	0.0	0.0	0.0	15.0	

4.4 MEANS OF COMPARISON

To determine whether parametric tests could be used, a One-Sample Kolmogorov-Smirnov Test was done. The normal distribution of the CARAT test is shown in Table 4-3. The One-Sample Kolmogorov-Smirnov test for the normality revealed no significant differences against the normality of the variables (p> 0.05). Hence it can be inferred that the distributions are normal and that the t-test and ANOVA can be used.

Table 4-3: One-Sample Kolmogorov-Smirnov Normal Distribution Test

		Carat base line	Carat first visit	Carat second visit
N		20	20	20
Normal Parameters[a,b]	Mean	1.5300	1.9305	2.2125
	Std. Deviation	1.12140	.80939	.76807
Most Extreme Differences	Absolute	.239	.215	.165
	Positive	.239	.215	.153
	Negative	-.195	-.170	-.165
Test Statistic		.239	.215	.165
Asymp. Sig. (2-tailed)		.004[c]	.016[c]	.158[c]

a. Test distribution is Normal.

b. Calculated from data.

c. Lilliefors Significance Correction.

4.4.1 CARAT Intra-Group Relationship

The intra-group relationship of the CARAT score for both Treatment and Placebo is explained in this section.

The mean, standard deviation and correlation coefficient for the CARAT treatment group is shown in Table 4-4. As indicated by the level of significance, it was observed that there was a strong positive correlation between CARAT baseline and CARAT first visit (r = 0.913; $p< 0.001$) with respect to the pair 1 scoring pattern. Similar scoring pattern was also observed in pair 2 and 3, respectively, which shows a strong positive correlation between CARAT baseline and CARAT second visit (r = 0.819; $p<0.001$) as well as CARAT first visit and CARAT second visit (r = 0.766; $p<0.01$). An examination of the means for CARAT baseline and CARAT first visit for example, indicates that the CARAT first visit values are significantly higher than the CARAT baseline values. A similar pattern is observed for CARAT second visit and CARAT baseline values. Overall, it can be gathered that the CARAT second visit had the highest mean (2.193±0.82), whereas the CARAT baseline had the lowest mean value (1.487±1.23).

Moreover, the independent paired sample test for the CARAT treatment is presented in Table 4-5. As gleaned from the aforementioned table, it can be observed that there were statistical significant differences ($p< 0.05$) with Pair 1(Carat baseline and Carat first visit) as well as Pair 2 (Carat baseline and Carat second visit). Interestingly, there was no significant difference ($p>0.05$) observed with respect to Pair 3 (Carat first visit and carat second visit).

Table 4-4: Mean, standard deviation, and correlation for Treatment sample

		Mean	N	Std. Deviation	Std. Error Mean	Correlation	*P*-Value
Pair 1	Carat base line	1.4870	10	1.23975	.39204	.913	.000
	Carat first visit	1.9730	10	.86481	.27348		
Pair 2	Carat base line	1.4870	10	1.23975	.39204	.819	.004
	Carat second visit	2.1930	10	.82312	.26029		

Pair 3	Carat first visit	1.9730	10	.86481	.27348	.766	.010
	Carat secondvisit	2.1930	10	.82312	.26029		

With reference to the CARAT placebo group in Table 4-6, a positive strong correlation was observed with respect to pair 1, that is CARAT baseline and CARAT first visit (r = 0.929; *p*< 0.001). Similarly, and with regards to the Pair 2 and 3 of the placebo group, there as positive strong correlation between CARAT baseline and CARAT second visit (r =0.875; *p*<0.001) as well as CARAT first visit and CARAT second visit (r = 0.713; *p* < 0.05), respectively. An examination of the means for CARAT baseline and CARAT first visit for example, indicates that the CARAT first visit values are significantly higher than the CARAT baseline values. A similar pattern is observed for CARAT second visit and CARAT baseline values. Overall, it can be gathered that the CARAT second visit had the highest mean (2.232±0.75), whereas the CARAT baseline had the lowest mean value (1.573±1.06).

Table 4-5: Independent Paired Samples Test for treatment

Paired Differences					T	df	Sig. (2-tailed)
Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
			Lower	Upper			
-.48600	.57241	.18101	-.89547	-.07653	-2.685	9	.025
-.70600	.73624	.23282	-1.23267	-.17933	-3.032	9	.014
-.22000	.57847	.18293	-.63381	.19381	-1.203	9	.260

Additionally, and as shown in Table 4-7, the independent pair test for the placebo group revealed statistically significant differences for Pair 1 and Pair 2 (p < 0.05). In contrast, there was however no significant difference for the Pair 3 (CARAT first and CARAT second visit).

Table 4-6: Mean, standard deviation and correlation for Placebo sample

		Mean	N	Std. Deviation	Std. Error Mean	Correlation	*P*-Value
Pair 1	Carat base line	1.5730	10	1.05533	.33372	.929	.000
	Carat first visit	1.8880	10	.79442	.25122		
Pair 2	Carat base line	1.5730	10	1.05533	.33372	.875	.001
	Carat second visit	2.2320	10	.75301	.23812		
Pair 3	Carat first visit	1.8880	10	.79442	.25122	.713	.021
	Carat second visit	2.2320	10	.75301	.23812		

Table 4-7: Independent Paired Samples Test for Placebo

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	Carat base lin - Carat week one	-.31500	.43334	.13703	-.62499	-.00501	-2.299	9	.047
Pair 2	Carat base lin - Carat week two	-.65900	.53807	.17015	-1.04391	-.27409	-3.873	9	.004
Pair 3	Carat week one - Carat week two	-.34400	.58760	.18581	-.76434	.07634	-1.851	9	.097

4.4.2 Inter-Group Analysis

The inter-group relationship of CARAT score for both Placebo and Complex is explained in this section.

From Table 4-8, it was noted that the highest the mean value for the placebo were slightly higher (1.57±1.01) when compared against the treatment group (1.49±1.23) for the CARAT baseline. Similar trend was also observed for the CARAT second visit, as the placebo had a higher mean (2.23±0.75) when compared against the treatment group (2.19±0.82). In contrast, the reversed was the case for the CARAT first visit. As the treatment group had a slightly higher mean (1.97±0.86) when compared against the placebo group (1.89±0.79). Overall, the ANOVA result presented in Table 4-9 showed that both treatment and placebo (combined group) exhibited no statistical differences (p>0.05). This implies that the means are not that different between the treatment and placebo groups.

Table 4-8: Mean, Standard deviation, minimum and range for both Complex and Placebo

		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
						Lower Bound	Upper Bound		
Carat baseline	Treatment	10	1.4870	1.23975	0.39204	0.6001	2.3739	0.00	3.00
	Placebo	10	1.5730	1.05533	0.33372	0.8181	2.3279	0.00	3.00
	Total	20	1.5300	1.12140	0.25075	1.0052	2.0548	0.00	3.00
Carat first visit	Treatment	10	1.9730	0.86481	0.27348	1.3544	2.5916	0.93	3.00
	Placebo	10	1.8880	0.79442	0.25122	1.3197	2.4563	1.07	3.00
	Total	20	1.9305	0.80939	0.18098	1.5517	2.3093	0.93	3.00
Carat second visit	Treatment	10	2.1930	0.82312	0.26029	1.6042	2.7818	0.27	2.93
	Placebo	10	2.2320	0.75301	0.23812	1.6933	2.7707	0.47	3.00
	Total	20	2.2125	0.76807	0.17174	1.8530	2.5720	0.27	3.00

Table 4-9: ANOVA Table

		Sum of Squares	df	Mean Square	F	Sig.
Carat base line	Between Groups	.037	1	.037	.028	.869
	Within Groups	23.856	18	1.325		
	Total	23.893	19			
Carat first visit	Between Groups	.036	1	.036	.052	.822
	Within Groups	12.411	18	.689		
	Total	12.447	19			
Carat second visit	Between Groups	.008	1	.008	.012	.913
	Within Groups	11.201	18	.622		
	Total	11.209	19			

4.5 DAILY LOG BOOK

The combined reliability scores by weeks are shown in Table 4-10. The scores exceed the recommended value of 0.700. This implies a high degree of consistent scoring in the survey.

Table 4-10: Survey scales and Predictor variables in Daily log Book

Survey scales	Predictor variables	Number of Items	Cronbach's Alpha score
1	Week 1	119	0.893
2	Week 2	119	0.912
3	Week 3	119	0.912
4	Week 4	119	0.920

4.5.1 Inter Group Comparison

The inter-group relationship of the respondents for the daily log book for combined group by weeks is explained in this section.

A repeated measure ANOVA was used to test for the difference across weeks in the rhinitis scores. As shown in Table 4-11, both the Pillai's and Wilk's lambda analysis indicates that the total number of symptoms present differs significantly across the 4 week periods (F= 79.510, p<.0005). More so, the post hoc comparison tests in Table 4-12 show that the number of symptoms is significantly more in week 1 than in the subsequent weeks. There was however, no statistical significant difference in respect to week 3 and week 4 (p> 0.05).

Table 4-11: Multivariate Analysis of Daily log Book

	Value	F	Hypothesis df	Error df	Sig.	Partial Eta Squared
Pillai's trace	0.505	79.510[a]	3.000	234.000	0.000	0.505
Wilks' lambda	0.495	79.510[a]	3.000	234.000	0.000	0.505
Hotelling's trace	1.019	79.510[a]	3.000	234.000	0.000	0.505
Roy's largest root	1.019	79.510[a]	3.000	234.000	0.000	0.505

Each F tests the multivariate effect of Week. These tests are based on the linearly independent pairwise comparisons among the estimated marginal means.a Exact stats

Table 4-12: Post Hoc comparison by weeks of Daily log Book

(I) Week		Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b] Lower Bound	Upper Bound
1	2	.176*	0.013	0.000	0.151	0.201
	3	.211*	0.014	0.000	0.183	0.239
	4	.214*	0.015	0.000	0.184	0.244
2	1	-.176*	0.013	0.000	-0.201	-0.151
	3	.035*	0.008	0.000	0.019	0.051
	4	.037*	0.011	0.001	0.016	0.059
3	1	-.211*	0.014	0.000	-0.239	-0.183

	2	-.035*	0.008	0.000	-0.051	-0.019
	4	0.003	0.009	0.777	-0.016	0.021
4	1	-.214*	0.015	0.000	-0.244	-0.184
	2	-.037*	0.011	0.001	-0.059	-0.016
	3	-0.003	0.009	0.777	-0.021	0.016

Based on estimated marginal means

*. The mean difference is significant at the .05 level.

Figure 4-2 illustrates the differences in weeks for the daily log book. Statistically, there were no significant differences in the weeks needed to treat the symptoms of rhinitis asthma ($p > 0.05$). A noteworthy result is that the mean for treatment group were consistently higher when compared against the placebo with the exception of week two.

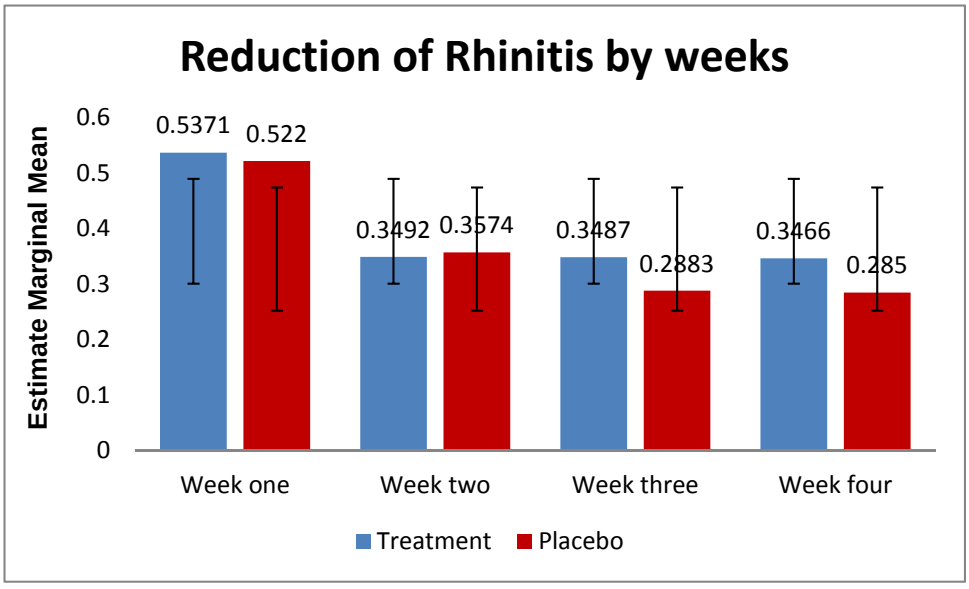

Figure 4-2: Mean Estimate showing the reduction of Rhinitis by weeks for the combined group.

4.6 CONCLUSION

In summary, it can be deduced that there is a small effect from treatment, although not significant. Furthermore, the repeated ANOVA measure analysis also shows that the type of treatment has no significant effect on these measures. Overall, it can be gathered that treatment had a better effect in the management of rhinitis symptoms. This chapter therefore conclusively showed that rhinitis and asthma are chronic conditions and need to be treated as such with chronic homoeopathic treatment. Hence, acute treatment over a few weeks is unlikely to have any significant effect in alleviating the symptoms.

CHAPTER 5 - DISCUSSION

5.1 INTRODUCTION

This study was designed to determine the effect of homoeopathic *Similisan Nasal Allergy Relief Spray*® in the management of allergic rhinitis in terms of CARAT questionnaire. Control of Allergic Rhinitis and Asthma Test was used to evaluate the subjective symptoms such as nasal itching, sneezing, ocular redness, nasal congestion, watery eyes and itching of throat, ears.

In total, 33 participants were seen but 3surveys were discarded as maximum number was reached. All 30 participants where between the ages of 18 and 50 with signs and symptoms of allergic rhinitis. The study was randomised by a supervisor, 15 participants were placed on medication and 15 were placed on placebo.

5.2 STATISTICAL ANALYSIS REPORT

5.2.1 Age distribution

The age distribution of the participants was between the ages of 18-50 years (Figures 4-1). The figure illustrates that 62% of the participants in the treatment group were between 18-26 years, 30% were aged between 27-34 years and 8% were aged between 41-50 years. It also illustrates the age distribution of participants in the placebo group, whereby 71% were between the age of 18-26 years, 18% were between the age of 27-34 years and 11% where between the age of 41-50 years. Most of the participants are young due to the fact the study was conducted at the Durban University of Technology. The participants are from Durban and some of them live near the harbour.

Before the study commenced participants graded their overall allergic rhinitis symptoms. This indicates the severity of the AR of the participants in the control group and treatment group. It was established that variances in the severity was minimal between the control and treatment group. 0.539 for the treatment group and 0.570 for the control group, see Table-4.1.

5.2.2 CARAT report

Questionnaires were completed to establish whether participants had allergic rhinitis, to assess whether participants were eligible for the study and to derive descriptive statistics. Before the study commenced participants graded their overall AR symptoms, as indicated in Table 4-3, these shows significant high scoring. In the CARAT intra-group relationship, it indicates that there was a strong positive correlation between CARAT base line and CARAT first visit similar with CARAT second visit and third visit but the CARAT second visit showed significant improvement in participant symptoms (Table 4-4).

The inter-group relationship of CARAT score for both Placebo and nasal spray is in this section from Table 4-8, it was noted that the placebo group had highest the mean value and slightly higher when compared against the treatment group (Table 4-8) for the CARAT baseline. In contrast, the reverse was the case for the CARAT first visit. As the treatment group had a slightly higher mean (1.97±0.86) when compared against the placebo group (1.89±0.79). Overall, the ANOVA result presented in Table 4-9 showed that both treatment and placebo (combined group) exhibited no statistical differences (p>0.05). This implies that the means are not that different between the treatment and placebo groups.

The CARAT questionnaire showed no statistical difference between visits or between the treatment group and the placebo. From this it can be deduced that the treatment was not effective in alleviating the symptoms of AR.

5.2.3 Daily log book report

The daily log books where given at the beginning of the study so that participants can grade their symptoms.:

1 = Yes

2= No

The combined reliability scores by weeks shown in Table 4-10 the scores exceed the recommended value of 0.700. This implies a high degree of consistent scoring in the survey.

The inter-group relationship of the respondents for the daily log book for combined group by week measures the repeated ANOVA (Table 4-12) indicates that the total number of symptoms present differs across the 4-week period. The post hoc comparison tests in Table 4-13 show that the number of symptoms is significantly more in week 1 than in the subsequent weeks but there is no statistical significant difference in respect to week 3 and week 4 (p> 0.05).

This means that the mean results for the treatment group were consistently higher when compared against the placebo with the exception of week two. The limited effects on the treatment group can be attributed to the subjectivity of the questionnaire and also on the mode of treatment, homoeopathic complex. This can be sustained by Vithoulkas (2002) that a combination of remedies is used for symptomatic treatment of conditions and does not aim to eliminate the cause of ailment.

The positive significance in the placebo group can be attributed to the patients' confidence in the research, their optimism and hope that homoeopathic treatment will improve their symptoms. As stated by Beers *et al.* (2006), the remarkable component of placebo is the anticipation and expectation associated with the medication and spontaneous change or natural history of the condition.

This was an extensive study. After completion of the study individual case history and follow up consultation was reviewed, it was apparent that most of the participants experienced amelioration of symptoms during the case of the treatment but these symptoms returned before the end of the study. This indicates that the relief experienced was transient.

5.3 FACTORS CONTRIBUTING TO THE RESULT OF THE STUDY

There are two main categories for allergic rhinitis which is seasonal and perennial (Colledge*et al.*2010). As stated by Cox *et al.* (2011) patients with seasonal allergic rhinitis experience symptoms in the presence of allergens such as pollen or mold sores. Conversely patients with perennial allergic rhinitis have symptoms throughout the year.

Different types of allergens which cause AR symptoms vary extensively with a number of contributing factors, in particular climate and environment. The length of exposure to the allergen is responsible for seasonal AR is often dependent on the geographic location and general environment in which the patient lives (Wallace *et al.*2008).

Changes in temperature and precipitation regimes due to global warming may also affect the abundance of fungal spores' indoor air following extreme floods or droughts and rising temperature lead to longer allergy season and can make air pollution worse (Jacobson 2010; Roger 2006). Heavy rainfall and flooding events are often followed by indoor fungal spores due to increased dampness (Ziska, Epstein and Rogers 2008). Ragweed the primary allergen trigger of fall of hay fever, grows faster, produces more pollen and has higher allergenic content under increased carbon dioxide levels and warm temperatures (Rogers*et al.* 2006).

Change in temperature or humidity can trigger the membranes insides the nose to swell, runny, itch or stuffy. During the study there was a severe change of weather which may have affected the patients' allergic rhinitis symptoms.

As seen in Table 5-1 and 5-2 (Custom Weather 2017), October and November 2016 there was high humidity levels, this could result into abundance of pollen or mold spores floating in the air. Mold spore grow on dead leaves and release spores into the air that may peak on dry windy, damp or rainy days, common throughout spring and summer (Bush *et al.* 2006). This sudden change of weather could have affected the results.

High & Low Weather Summary for October 2016

	Temperature	Humidity	Pressure
High	31 °C (15 Oct, 13:00)	89% (27 Oct, 20:54)	1029 mbar (27 Oct, 20:54)
Low	10 °C (4 Oct, 05:00)	40% (2 Oct, 14:46)	1000 mbar (6 Oct, 15:00)
Average	19 °C	74%	1017 mbar

* Reported 1 Oct 00:00 — 31 Oct 23:00, Durban, Weather by CustomWeather, © 2017

Table 5-1 Summary of weather in Durban October 2016 (Custom Weather, 2017)

High & Low Weather Summary for November 2016

	Temperature	Humidity	Pressure
High	37 °C (21 Nov, 14:00)	100% (28 Nov, 10:00)	1028 mbar (28 Nov, 10:00)
Low	15 °C (19 Nov, 05:00)	30% (21 Nov, 13:00)	999 mbar (12 Nov, 12:48)
Average	21 °C	74%	1016 mbar

* Reported 1 Nov 00:56 — 30 Nov 23:00, Durban, Weather by CustomWeather, © 2017

Figure 5-2 Summary of weather in Durban November 2016 (Source: Custom Weather, 2017)

Exposure to pollutants such as oxide of nitrogen, sulphur dioxide or black smoke are considered as contributing in both aetiology and exacerbation of allergic airway disease (Gershwin 2003). Two participants` in the study AR symptoms were triggered by cigarette smoking and they both live with people who smoke. Therefore, the symptoms are reversible and the spontaneous exposure to allergens triggering factors whilst under treatment.

As this study was conducted outside the clinical setting, the patient compliance may have affected the results as the patients were instructed to take the medication as prescribed. There is no means to gauge whether allergens exposure remained constant or not. There is a 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 symptoms outside the specified times. It is also possible that participants indeed have taken medicine and not reported it.

5.4 ADVERSE EFFECTS NOTED IN THE STUDY

As homoeopathic treatment is proved individually and not in groups their interaction with each other are not certain and it is impossible to tell how they will react in the body and which medicine in the combination actually affected the improvement or cure. It is then also impossible to tell which medicine causes aggravation.

*Sabadillaofficinarum*and *Galphimiaglauca*are particularly known for their allergic vasomotor action of the eyes and nose with burning discharge (Reckeweg 2002: Riley 2012). Four participants who were on treatment had red and itchy eyes after taking treatment which subsided after 3 days after taking medication. This kind of reaction was expected due to the homoeopathic aggravation because they had this symptom before.

As been stated by Riley (2012) and Juneja (2005), *Cardiospernumhallicacaum* and *Luffa operculata*, both have anti-inflammatory effects. During the first week of treatment most participants complained of frequent sneezing and thick yellow discharge, which subsided one week after taking treatment.

Homoeopathic treatment is usually distinctive to each individual symptom, even though the participants in this study were treated with the same medication this may explain the inadequate response to treatment.

5.5 CONCLUSION

The treatment group was effective in managing the mean symptom severity over a small period of time, however the decrease in symptoms did not continue due to the contributing factors, like the of change of weather. The action of the homoeopathic remedies could have accounted to continue to decrease the symptoms if the medication was administrated for a long period of time.

It can be concluded that *Similasan Nasal Allergy Relief Spray* ® was not effective in treating allergic rhinitis due to factors that affected the study. The study was done in a short period of time and high exposure to certain allergens during the time of study.

CHAPTER 6 - CONCLUSION

6.1 CONCLUSION

This research study determined the efficacy of *Similasan Nasal Allergy Relief Spray*® in management of allergic rhinitis in terms of CARAT questionnaire. Rhinorrhoea, sneezing, itching of the eyes and nasal congestion showed a statistically significant results but some of the participant's symptoms deteriorated after a period of improvement.

A statistically significant improvement occurred in some of the variables of the CARAT questionnaire (Appendix D) in both the treatment and the placebo group. However, the was no significant difference between treatment group and placebo group. Thus, it can be concluded that Similasan *Nasal Allergy Relief Spray* ® in terms of CARAT questionnaire was not effective.

Symptomatic results showed no significant effect to support the hypothesis that *Similisan Nasal Allery Relief Spray*®has a beneficial effect to decrease the symptoms of allergic rhinitis. This resulted in a no symptomatic relief of allergic rhinitis. Strongly repeated exposure to large amounts of aeroallergens, pollutants, cold dry air and humidity including smoke induce respiratory symptoms (Delgado *et al.*2006). This could be a possible reason why there was no statistical difference in comparison of the placebo and treatment group.

The original aim was to evaluate the efficacy of *Similasan Nasal Allergy Relief Spray*®. Statistical analysis carried out showed that there is a small effect on the treatment with no significant difference.

6.2 RECOMMENDATIONS

The following are recommendations that may be considered in order to improve the research study:

- The research study should be done for a longer period of at least 3 months to establish long effects of medication as well as to effectively cover the seasonal changes that may affect allergic rhinitis.

- The sample size should be increased to improve statistical evaluation. In this research study there were only 30 participants. It is recommended that future studies a=consider sample sizes of about 60 participants.

- Making use of skin prick test and RAST blood test as measuring tools to determine the allergic factors that may be triggering the allergic rhinitis prior to the research.

- It is suggested that participants begin and end trial at the same time so that the trial is conducted at the same climate and season for all participants to avoid any climatic and seasonal influence for the research study (Wallace *et al.* 2008).

- The aetiology of allergic rhinitis should be established prior to the start of research, so that participants of the same aetiology group can be grouped together.

- Do the study in the same geographic area and occupational environments, to avoid different exposure to allergens that may influence the results of the study.

- Research should be conducted using *Similimum* treatment for allergic rhinitis that will then take into account each individual rather than using a complex for all patients.

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Appendix A: Information letter for participants

INSTITUTIONAL RESEARCH ETHICS COMMITTEE (IREC)

LETTER OF INFORMATION

Dear Participant

Thank you for agreeing to participate in this study.

Title of the Research Study: The efficacy of a homoeopathic *Similasan Nasal Allergy Relief Spray*® in the management of allergic rhinitis in terms of the CARAT questionnaire.

Principal Investigator/s/researcher: Miss ThobileTshabalala.

Co-Investigator/s/supervisor/s: Dr I Couchman. (M:TechHom.)

Dr.S. Nienaber (M:TechHom)

Brief Introduction and Purpose of the Study: The purpose of this proposed randomised, double-blind randomised controlled study is to determine the efficacy of a homoeopathic *Similasan Nasal Allergy Relief Spray*® in the management of allergic rhinitis in terms of the CARAT questionnaire.

Recent studies suggest that allergic rhinitis (AR) is the most common allergic condition and one of the most common of all minor afflictions. The prevalence of the disorder is increasing. This may result in significant impairment to quality of life, sleep and work performance (Small and Kim 2011). Small and Kim (2011) also state that AR is responsible for 2.5% of all doctor visits. Antihistamines, corticosteroids and other drugs used to treat allergic rhinitis make up a significant fraction of both prescription and over-the-counter drug sales each year. These drugs may help for a certain period of time but have side effects that disrupt normal functioning like causing reduced sense of smell, loss of taste, epistaxis, pharyngitis and headache (Small 2011).

Allergic rhinitis (AR) is described as inflammation of the nasal mucosa and includes common symptoms like nasal discharge, itching, sneezing, nasal blockage, or congestion. AR is an immunoglobin E (IgE)-mediated immunologic response of the nasal mucosa to airborne allergens such as pollens, dust, or animal dander. Inhalation of allergens in individuals with a sensitized immune system produces degranulation of mast cells with the release of chemical mediators.

Outline of the Procedures: The consultations where data relating to AR will be collected will take place at the Durban University of Technology (DUT), Homoeopathic Day Clinic (HDC). The total duration of the study is 4 weeks with only 3 consultations. The Initial consultation will be an hour long and thereafter the follow up consultations will be about 30 minutes long. You will be requested to complete the consent form before you may participate in this study. On consenting to participate, you will be requested to complete the scales that will be explained to you. The completion of the scales may take 10 minutes. These scales will be completed before each consultation. A detailed case and physical examination will be performed.

Non-participation: You are not forced to participate in this study. Participation in this study is voluntarily. If you don't participate in this study it will not affect the service offered to you by the HDC.

Risks or Discomforts to the Participant: You will not experience any discomfort from participating in this study.

Benefits: The information given by you will help to draw conclusions about the efficacy of a homoeopathic *Similasan Nasal Allergy Relief Spray*® in the management of allergic rhinitis.

What is expected of the participant?

You will be applying a treatment spray into your nose as often as needed. Initial exacerbation of symptoms may occur.You are advised not to apply any other AR treatment during the study period as this could affect the validity of the results. Full instructions on the application of the nasal spray will be given to you. There is a 50% chance that you will be in a treatment group that will get *Similasan Nasal Allergy Relief Spray*® or in a control group that will get a saline solution nasal spray comprising inactive ingredients: purified water, *Sodium chloride*. Only the treatment spray has therapeutic properties.

Reason/s why the Participant May Be Withdrawn from the Study: You are free to withdraw from the study at any time without any form of penalty.

Remuneration: There is no remuneration for participating in this study.

Costs of the Study: You will not be expected to cover any costs towards the study.

Confidentiality: Please do not write your personal information like name, contact details on the scales. All data collected will be pooled to ensure anonymity. Pooled data will be communicated scientifically. Data will be stored in a locked cupboard for 5 years

Research-related Injury: There are no injuries that you may be exposed to during the course of the study.

Please inform the researcher/ supervisors of the study if any of the following is experienced:

- Susceptibility to nose bleeds.
- If you are prone to ear, nose or throat sensitivity.
- Any discomfort attributed to the treatment.
- Or for any queries regarding your treatment.

Please stop use and consult the researcher/ supervisors if symptoms persist beyond 7 days or if they worsen. You are advised to not use the spray if bottle seal is not intact.For your protection do not use if tamper evident seal is missing or open. Please replace cap tightly after every use. To avoid contamination, do not touch the tip of the container to any surface. The use of this container by more than one person may spread infection therefore you are advised to not share the nasal spray with anyone.

Persons to Contact in the Event of Any Problems or Queries:

Ms. T. Tshabalala (Student) 072 990 7483.

Dr. I Couchman (supervisor) 031 373 2482

Dr. S. Nienaber (co-supervisor) 031 373 2041

The Institutional Research Ethics administrator: - 031-373 2900. Complaints can be reported to the DVC: TIP F. Otieno on 031-3732382 or dvctip@dut.ac.za.

Appendix B: Consent form for participants

INSTITUTIONAL RESEARCH ETHICS COMMITTEE (IREC)

CONSENT

Statement of Agreement to Participate in the Research Study:

- I hereby confirm that I have been informed by the researcher, _____ (name of researcher), about the nature, conduct, benefits and risks of this study - Research Ethics Clearance Number: _____,
- I have also received, read and understood the above written information (Participant Letter of Information) regarding the study.
- I am aware that the results of the study, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a study report.
- In view of the requirements of research, I agree that the data collected during this study can be processed in a computerised system by the researcher.
- I may, at any stage, without prejudice, withdraw my consent and participation in the study.
- I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.
- I understand that significant new findings developed during the course of this research which may relate to my participation will be made available to me.

_____	_____	_____	_____
Full Name of Participant	Date	Time	Signature / Right Thumbprint

I, _____ (name of researcher) herewith confirm that the above participant has been fully informed about the nature, conduct and risks of the above study.

_____	_____	_____
Full Name of Researcher	Date	Signature

_____	_____	_____
Full Name of Witness (If applicable)	Date	Signature

_____	_____	_____
Full Name of Legal Guardian (If applicable)	Date	Signature

Appendix C: Daily log book

Azevedo*et al*. 2013, Seidmam*etal.*2015

Symptom	Yes	No
1. Sneezing over and over again, especially after you wake up in the morning.		
2. A runny nose.		
3. A tickle in your throat or coughing caused by postnasal drip.		
4. Watery, itchy eyes.		
5. This may be allergic pinkeye.		
6. Itchy ears, nose, and throat.		
7. Other symptoms that		
8. may take longer to appear include:		
9. A stuffy nose, possibly with sniffing. This is the most common symptom in children.		
10. Breathing through your mouth because your nose is blocked.		
11. Rubbing your nose. Children tend to do this.		
12. Eyes being sensitive to light		
13. Feeling tired, grumpy, or moody.		
14. Not sleeping well.		
15. A long-lasting (chronic) cough.		

16. Pressure in your ear		
17. Having a hard time hearing.		
18. Discomfort or pain in your face		
19. Dark circles or patches under your eyes		

.

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Appendix D: Control of Allergic Rhinitis and Asthma Test questionnaire (CARAT)

CARAT CONTROL OF ALLERGIC RHINITIS AND ASTHMA TEST

DATE:___/___/_____ IDENTIFICATION:_____

Appendix 1. Control of Allergic Rhinitis and Asthma Test

Please mark the following boxes with a cross (☒).

Due to your allergic respiratory diseases (asthma, rhinitis, allergies) in the last four weeks, on average, **how many times did you have**:

	Never	1 or 2 days per week	More than 2 days per week	Almost every day
1. Blocked nose?	☐ 3	☐ 2	☐ 1	☐ 0
2. Sneezing?	☐ 3	☐ 2	☐ 1	☐ 0
3. Itchy nose?	☐ 3	☐ 2	☐ 1	☐ 0
4. Runny nose?	☐ 3	☐ 2	☐ 1	☐ 0
5. Shortness of breath/dyspnoea?	☐ 3	☐ 2	☐ 1	☐ 0
6. Wheezing in the chest?	☐ 3	☐ 2	☐ 1	☐ 0
7. Chest tightness upon physical exercise?	☐ 3	☐ 2	☐ 1	☐ 0
8. Tiredness/ limitations in doing daily tasks because of your allergic respiratory diseases?	☐ 3	☐ 2	☐ 1	☐ 0
9. Woke up during the night because of your allergic respiratory diseases?	☐ 3	☐ 2	☐ 1	☐ 0

In the last 4 weeks, because of your allergic respiratory diseases (asthma, rhinitis, allergies), how many times did you:	I'm not taking any medicines	Never	Less than 7 days	7 or more days
1. increased the use (dosage or frequency) of your medicines?	☐ 3	☐ 3	☐ 2	☐ 0

_____ *Score*
(Sum of all 10 questions, 0 - worst, best - 30)

Date __/__/____

Appendix E (a): Permission Application Letter to use Homoeopathic Day Clinic (HDC) –HOD LETTER

PO Box 1748
Harrismith
9880

Faculty of Health Clinic Director &
Homoeopathic Day Clinic Coordinator
P.O. BOX 1334
Durban
4000

Dear Dr Hall

Permission Application Letter to use the Homoeopathic Day Clinic (HDC)

Thank you for reading this letter. My name is Miss ThobileTshabalala (20610025). I am currently registered for M. Tech. Homoeopathy and I am requesting to conduct my research study at the Homoeopathic Day Clinic (HDC). The tittle of my study is: **The efficacy of a homoeopathic *Similasan Nasal Allergy Relief Spray*® in the management of allergic rhinitis in terms of the CARAT questionnaire**

Outline of the Procedures: Outline of the Procedures: The consultations where data relating to Allergic rhinitis (AR) will be collected will take place at the Durban University of Technology (DUT), Homoeopathic Day Clinic (HDC). The sample size is 30 consenting participants. The total duration of the study is 1 month (4 weeks) with only 3 consultations.

The Initial consultation will be about an hour long and thereafter the follow up consultations will be about 30 minutes long. Participants will be requested to complete the consent form

before they may participate in this study. On consenting to participate they will be requested to complete the scales that will be explained to them.

The completion of the scales may take 15-20 minutes. These scales will be completed before each consultation.

Hope my request will be acknowledge.

Yours sincerely.

_____

Miss ThobileTshabalala (20610025)-Researcher: 072 990 7483 thobilet@ymail.com

_____

Dr. I Couchman (Supervisor) 031 373 2482 ingridc@dut.ac.za

Dr. (Co-supervisor) 031 373 2041 dr.silvananienaber@gmail.com

Appendix E (b): Permission Application Letter to use Homoeopathic Day Clinic (HDC)-

Homoeopathic Clinic Director & Coordinator:

PO Box 1748
Harrismith
9880

Faculty of Health Clinic Director &
Homoeopathic Day Clinic Coordinator
P.O. BOX 1334
Durban
4000

Dear Dr Korporaal and Dr Nienaber

Permission Application Letter to use the Homoeopathic Day Clinic (HDC)

Thank you for reading this letter. My name is Miss ThobileTshabalala (20610025). I am currently registered for M. Tech. Homoeopathy with the Durban University of Technology and I am requesting to conduct my research study at the Homoeopathic Day Clinic (HDC). The tittle of my study is: **The efficacy of a homoeopathic *Similasan Nasal Allergy Relief Spray*® in the management of allergic rhinitis in terms of the CARAT questionnaire.**

Outline of the Procedures: Outline of the Procedures: The consultations where data relating to Allergic rhinitis (AR) will be collected will take place at the Durban University of Technology (DUT), Homoeopathic Day Clinic (HDC). The sample size is 30 consenting participants. The total duration of the study is 1 month (4 weeks) with only 3 consultations. The Initial consultation will be about an hour long and thereafter the follow up consultations will be about 30 minutes long. Participants will be requested to complete the consent form before they may participate in this study. On consenting to participate they will be requested to complete the scales that will be explained to them.

The completion of the scales may take 15-20 minutes. These scales will be completed before each consultation.

Hope my request will be acknowledged.

Yours sincerely._____

Miss ThobileTshabalala (20610025)-Researcher: 079 990 7483 thobilet@ymail.com

_____Dr. I Couchman (Supervisor) 031 373 2482 ingidc@dut.ac.za

Appendix E (c): Application Letter to use Notice Boards to paste advert for research

PO Box 1748
Harrismith
9880

Faculty of Health Sciences
Department of Homoeopathy
P.O. BOX 1334
Durban
4000

To whom it may concern.

Dear Sir/ Madam**Permission Letter to use Notice Boards for pasting research advert**Thank you for reading this letter. My name is Miss ThobileTshabalala (20610025). I am currently registered for M. Tech. Homoeopathy and I am requesting to conduct my research study at the Homoeopathic Day Clinic (HDC). The tittle of my study is: **The efficacy of a homoeopathic *Similasan Nasal Allergy Relief Spray*® in the management of allergic rhinitis in terms of the CARAT questionnaire**

Outline of the Procedures: Outline of the Procedures: The consultations where data relating to Allergic rhinitis (AR) will be collected will take place at the Durban University of Technology (DUT), Homoeopathic Day Clinic (HDC). The sample size is 30 consenting participants. The total duration of the study is 1 month (4 weeks) with only 3 consultations.

The Initial consultation will be about an hour long and thereafter the follow up consultations will be about 30 minutes long. Participants will be requested to complete the consent form

before they may participate in this study. On consenting to participate they will be requested to complete the scales that will be explained to them.

The completion of the scales may take 15-20 minutes. These scales will be completed before each consultation.

Hope my request will be acknowledged.

Yours sincerely.

_____

Miss ThobileTshabalala (20610025)-Researcher: 079 270 8882 thobilet@ymaoil.com

_____

Dr. I Couchman (Supervisor) 031 373 2482 ingridc@dut.ac.za

Dr. S Nienabe (Co-supervisor) 031 373 2041 dr.silvananienaber@gmail.com

Appendix E (d): Permission Application Letter to use Homoeopathic Day Clinic (HDC)

Director: Research and Postgraduate Support

PO Box 1748
Harrismith
9880

Faculty of Health Clinic Director &
Homoeopathic Day Clinic Coordinator
P.O. BOX 1334
Durban
4000

Dear Professor Moyo**Permission Application Letter to use the DUT facility and staf**

Thank you for reading this letter. My name is Miss ThobileTshabalala (20610025). I am currently registered for M. Tech. Homoeopathy with the Durban University of Technology and I am requesting to conduct my research study at the Homoeopathic Day Clinic (HDC). The tittle of my study is: **The efficacy of a homoeopathic *Similasan Nasal Allergy Relief Spray*® in the management of allergic rhinitis in terms of the CARAT questionnaire**

Outline of the Procedures: Outline of the Procedures: The consultations where data relating to Allergic rhinitis (AR) will be collected will take place at the Durban University of Technology (DUT), Homoeopathic Day Clinic (HDC). The sample size is 30 consenting participants. The total duration of the study is 1 month (4 weeks) with only 3 consultations.

The Initial consultation will be about an hour long and thereafter the follow up consultations will be about 30 minutes long. Participants will be requested to complete the consent form

before they may participate in this study. On consenting to participate they will be requested to complete the scales that will be explained to them.

The completion of the scales may take 15-20 minutes. These scales will be completed before each consultation.

Hope my request will be acknowledged.

Yours sincerely.

_____

Miss ThobileTshabalala (20610025)-Researcher: 079 990 7483 thobilet@ymail.com

_____

Dr. I Couchman (Supervisor) 031 373 2482 ingridc@dut.ac.za

Dr. S Nienaber (Co-supervisor) 031 373 2041 dr.silvananienaber@gmail.com

Appendix F: Sponsorship for Similasan Nasal Allergy Relief Spray®

On Tuesday, June 9, 2015 12:43 PM, Dorothy Lottering<dorothy@foodstate.co.za> wrote:

Hi

Thank You for wanting to use Similasan.

Please send me a copy of your proposal and I will get your products ready for you.

Kind Regards

Dorothy Lottering

Product Manager

Regal Nutrients (Pty) Ltd.

Tel: +27 11 036 9429

Direct fax: +27 086 723 7871

Cell: 0794986960

Email:dorothy@foodstate.co.za

From: ThobileTshabalala [mailto:thobilet@ymail.com]

Sent: 01 June 2015 01:09 PM

To: Dorothy Lottering

Subject: research material

Dear Ms Lottering

Thank you for your support.

Please find the attached letter regarding about the research

with thanks

ThobileTshabalala

student no. 206100225

thobilet@ymail.com

APPENDIX G: PERMISSION TO USE CARAT QUESTIONNAIRE

PO Box 1748

Harrismith

9880

South Africa

Dear Sir/ Madam

RE: PERMISSION LETTER TO USE CARAT QUESTIONNAIRE

My name is ThobileTshabalala currently registered for Master`s degree in Homoeopathy with the Durban University of Technology, Durban, South Africa.

I am requesting to use Control of Allergic Rhinitis and Asthma Test questionnaire, CARAT, for my research study. The title of the study is: **The efficacy of homoeopathic Similasan nasal spray in the management of allergic rhinitis in terms of the CARAT questionnaire**.

The aim of the study is to evaluate the efficacy homoeopathicSimilasan nasal spray, the management of individual symptom of allergic rhinitis, change in quality of life and the change in frequency administration of Similasan nasal spray as an indicator for the control of the study. I found questionnaire to be useful for my research study as it consist of questions I want to evaluate on.

I hope my request will be highly appreciated.

Thanking you in advance.

Miss ThobileTshabalala

Student no. 20610025

email address: thobilet@ymail.com

ThobileTshabalala Dear Sir/Madam I, ThobileTshabalala, masters student in Durban University of Technology in South Africa. Please find the attached letter. I hope my request will be acknowledge. with thanks ThobileTs

Jan 29 at 10:05 AM

Thobile Tshabalala On Friday, January 29, 2016 10:05 AM, ThobileTshabalala<thobilet@ymail.com> wrote: Dear Sir/Madam I, ThobileTshabalala, masters student in Durban University of Technology in South Africa. Please fi

Feb 10 at 9:23 AM

ThobileTshabalala Dear Sir/Madam I, ThobileTshabalala, masters student in Durban University of Technology in South Africa. Please find the attached letter. I hope my request will be acknowledge. with thanks ThobileTshabalala

Feb 10 at 9:26 AM

João A Fonseca <fonseca.ja@gmail.com>

To

ThobileTshabalala

Feb 10 at 2:45 PM

Dear ThobileTshabalala,

Thank you for your interest in using the carat questionnaire. In accordance with the user licence, available at caratnetwork.org, you may use the questionnaire in your project. Please give us feedback when your work gets published.

Kind regards,

João A Fonsec

DUT DURBAN UNIVERSITY OF TECHNOLOGY

APPENDIX H: ADVERT

Are you suffering from allergic rhinitis (hay-fever)?

Do you suffer from one of the following symptoms:

- Sneezing
- Itchy nose
- Nose congestion (runny nose)
- Itchy eyes
- Watery eyes
- Cough

If Yes, ...

A research study is been conducted in Durban University of Technology.

If you want to participate you can contact Thobile Tshabalala 072 990 7483

Durban University Homeopatic Daily Clinic 031 373 2041

Similasan

Appendix I: Manufacturing process of homoeopathic *Similasan Nasal Allergy ReliefSpray*® in accordance to the German Homoeopathic Pharmacopoeia method HAB3A

Active Ingredients: Purpose

Cardiospermum 6X: itching, rhinitis, runny nose

Galphimiaglauca 6X: runny nose, watery eyes, sneezing

Luffa operculata 6X: runny nose, rhinitis, sinus congestion

Sabadilla 6X: sneezing, runny nose, itching, rhinitis

Other information:

Active ingredients are manufactured according to homoeopathic principles.

Inactive Ingredients:

Purified water, Sodium chloride

Uses:

According to homoeopathic principles, the active ingredients in this medication temporarily relieve minor symptoms of:
•allergies accompanied by runny nose, itching and/or burning of the nose, watery eyes, sneezing and swollen mucous membranes (congestion)
•acute and chronic allergic rhinitis
•post nasal drip caused by allergies
•sinus pressure caused by allergies

Warnings:
•Initial exacerbation of symptoms may occur.

•Use only if bottle seal is intact.
•Replace cap tightly after every use.
•To avoid contamination, do not touch the tip of the container to any surface.
•Discard open bottle after 6 months.
•The use of this container by more than one person may spread infection.
•For your protection do not use if tamper evident seal is missing or open.

Ask a doctor before use if you:
•are susceptible to nose bleeds
•are prone to ear, nose or throat sensitivity
Stop use and consult a doctor if:
•symptoms persist beyond 7 days or if they worsen

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

For adults and children, including toddlers & infants:
•remove tamper-evident plastic seal from bottle
•lift cap off bottle
•spray 1-3 times into each nostril
•use as needed
•replace cap after use

Appendix J: Posology and Dosage – How to apply treatment

Uses:

According to homoeopathic principles, the active ingredients in this medication temporarily relieve minor symptoms of:

•allergies accompanied by runny nose, itching and/or burning of the nose, watery eyes, sneezing and swollen mucous membranes (congestion).

•acute and chronic allergic rhinitis.

•post nasal drip caused by allergies.

•sinus pressure caused by allergies.

Warnings:

•Initial exacerbation of symptoms may occur.

•Use only if bottle seal is intact.

•Replace cap tightly after every use.

•To avoid contamination, do not touch the tip of the container to any surface.

•Discard open bottle after 6 months.

•The use of this container by more than one person may spread infection.

•For your protection do not use if tamper evident seal is missing or open.

Ask YOUR RESEARCHER/ RESEARCH SUPERVISOR before use if you:

•are susceptible to nose bleeds.

•are prone to ear, nose or throat sensitivity.

Stop use and consult a doctor if:

•symptoms persist beyond 7 days or if they worsen.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

1. Remove tamper-evident plastic seal from bottle.
2. Lift cap off bottle.

3. Spray 1-3 times into each nostril.
4. Use as needed.
5. Replace cap after use.

Appendix K: Case History Form

Date:_____/_____20_____

Title:

Surname……..First Name……..

Address (area where patient lives)……..

Contact Details:……..

Age……..Gender……

Marital status S/M/W/D (Please circle one)

Occupation (if unemployed, previous)……..

Children: Yes / No

(if yes –include gender & ages))1……2……3…….

4……5……6……7……8…….

Note:

- For any symptom: description now, **location, sensation, aetiology, modalities, concomitants, history, treatment/ management** so far.
- If no symptoms for any section of the case, write **NAD (No Appreciable Disease)** in the space provided.

---

1. **MAIN COMPLAINT/S**:

2. **PAST MEDICAL HISTORY:** Childhood illnesses, vaccinations, hospitalization, surgery. Accidents. Any other chronic illnesses still currently active e.g. hypertension, diabetes, asthma.

Allergies:_____

_____

If the patient does not understand the question, **do not pursue** it because you will not get useful information.

Smoking History: TYPE/BRAND_____

a) Number of cigarettes per day_____÷ 20 = A
b) Number of years _____= B
c) Number of pack years_____ = A x B

A pack year is a measure of exposure/ risk. Equivalent to smoking a 20-cigarette pack a day for one year. Work this out after taking the case if need be.

Alcohol History: TYPE OF DRING_____

a) Everyday? YES/ NO

b) Average number of drinks: cans/bottles/cartons beer_____

: bottle wine_____

: bottles spirits_____

---

3. **CURRENT MEDICINES**: Pharmaceutical or other, including **contraceptive pill/injection**, **HRT, sleeping tablets.**

Name:	For:

Current Supplements: (Vitamins, special drinks etc)

Name:	For:

4. **FAMILY MEDICAL HISTORY**:

MOTHER	FATHER

MOTHER'S MOTHER	FATHER'S MOTHER
MOTHER'S FATHER	FATHER'S FATHER
SIBLINGS	

_____

_____

5. **GASTROINTESTINAL**: Indigestion, heartburn, cramps, flatulence, appetite, cravings and aversions. Aggravations. Thirst.

TYPE OF DRINK:	QUANTITY PER DAY:
How many teaspoons of sugar in tea/ coffee?	How many cups a day?

6. **BOWEL FUNCTION**: Constipation, diarrhea, haemorrhoids (**detail is necessary only if problem is present**).

7. **URINATION**: Frequency, urgency, pain. (**detail is necessary only if UTI is present**). **Males over 40 years of age: strength of stream, stop-start, pain on ejaculation = Prostate.**

8. **MENSTRUATION**: Duration of overall cycle and regularity, duration of menses, volume, colour, consistency, pain, concomitants (e.g. headaches, constipation, diarrhea etc). **Menarche**. **Pre-menstrual symptoms**. Date of start of last menstrual period. **Pregnancies** – how many [reason for termination], complications, including post-natal depression. **Peri-menopause**: all of the above, as well as symptoms of hot flushes, dry skin, dyspareunia, mood swings. **Menopause**: age of onset. Brief history of menstruation i.e. any problems with menstruation?

9. **GENITALS**: Eruptions, discharge, infections. Females: history of thrush.

10. **SEXUALLY ACTIVITY**: Any problems? Desire/libido? History of **STD's. HIV STATUS**? **Cd4Count** if positive. When? **How many partners**? **Emotions regarding a positive status? Education regarding safe sex.**

11. **CHEST**: Problems with breast, breathing, cardiac.

12. **HEAD**: Ears, eyes, nose, throat/ voice. Headache: **painkillers**? Name, how many, how often? **Issue of medication overuse headache**(=**rebound headache** due to **addiction/dependency**. **Combination ingredient medicines worse than single ingredient medicines**. **Medication overuse** is defined in terms of **treatment days per month**, such that **treatment occurs at least three months**. The headache is present **on more than 15 days per month**.

13. **SLEEP:** Pattern, quality, position. Dreams (only worth pursuing if outstanding/ recurrent dreams)

14. **SKIN**: Current and history, rashes, warts, boils, pimples, easy bruising, rate of healing.

15. **MUSCULOSKELETAL**: Location, modalities, concomitants (e.g. weather changes).

16. **GENERAL**: Energy, weather preferences.

17. **MENTAL**: Ask things that have not already come up in the consultation. **Do not go over that material again unless it seems appropriate to do so**. If you had to **describe yourself**, what **type of person** would you say you

are? / What are you **characteristics**? / What is your **personality**? Anxiety / worries, anger, sadness/ depression. **Relationships**. **What makes you happy**?

INITIAL / 1ST CONSULTATION

HOMOEOPATHIC DAY CLINIC (D.U.T.)

CASE SUMMARY (SOAPE NOTE)

PATIENT DETAILS

Date:	**Patient's Name & Surname:**

S MAIN COMPLAINT(s)

O ON EXAMINATION

Vital Signs:	**Height:** **Weight:**
BP:	Observations(unusual)
Temp:	
Pulse:	

Resp:	

A DIAGNOSIS(Medical)

(**the ICD code must match the written diagnosis**)

ICD-10 code:	**Written diagnosis:**

CENTER OF CASE

(What needs to be addressed / changed)

CASE ANALYSIS

(Grading: very common=1; common=2; slightly characteristic=3;very characteristic=4;PQRS=5)

MENTAL	GENERAL	PARTICULAR

MIASM(S)

(Active - motivate)

P CASE MANAGEMENT

(Remedy differentials, posology and motivation)

(Patient management plan)

Next Follow up appointment: (eg. 3 weeks' time)

E PATIENT EDUCATION(Advice)

PRESCRIPTION

POWDERS	CREAM / TISSUE SALTS
Rx:	**Rx:**
Mitte:	**Mitte:**
Sig:	**Sig:**
Clinician's Auth:	**Clinician's Auth:**
VIALS	**DROPS/∅**
Rx:	**Rx:**
Mitte:	**Mitte:**
Sig:	**Sig:**
Clinician's Auth:	**Clinician's Auth:**

SIGNATURES

Clinicians Name:	**Students First Name:**
Clinicians Full Signature: **Date signed off:**	**Students Signature:**

Receptionist's signature:_____

Name of dispenser:	**Date dispensed:**

Appendix L: Physical Examination Form/ SOAPE Note-Case Summary

PATIENT DETAILS

DATE: / / 2015	**Patient's name & surname:**

S

MAIN COMPLAINT(S)

1.	**3.**
2.	**4.**

O

ON EXAMINATION

BP: / mmHg	**OBSERVATION (Unusual)**
PULSE: bpm	
RESP: bpm	
Temp:	
WEIGHT: kg	
URINE DIPSTICK:	**PREGNANCY:**

GENERAL EXAMINATION

Jaundice	
Anaemia	
Cyanosis	
Clubbing	

Oedema	
Dehydration	
Lymphadenopathy	

SYSTEM REVIEW

Respiratory Examination	
Cardiovascular Examination	
Abdominal Examination	
Musculoskeletal Examination	

A **DIAGNOSIS (MEDICAL)**

ICD-10 CODE:	**Written Diagnosis:**

CENTRE OF THE CASE

1.	**3.**
2.	**4.**

CASE ANALYSIS

MENTALS	GENERALS	PARTICULARS

RUBRICS [3]

P

REMEDY DIFFERENTIALS

1.	**4.**
2.	**5.**
3.	**6.**

PRESCRIPTION

1.
Rx:
Mitte:
Sig:

E

PATIENT EDUCATION/ADVICE

1.
2.
3.

SIGNATURES

Clinician's Name:	**Student's Name:**	**Dispenser's name:**
Clinician's Signature:	**Student's Signature**	**Dispenser's Signature:**
Date:	**Date:**	**Date:**

Appendix M: Follow up consultation form

FOLLOW – UP CONSULTATION

HOMOEOPATHIC DAY CLINIC (D.U.T.)

CASE SUMMARY (SOAPE NOTE)

PATIENT DETAILS

Date:	**Patient's Name & Surname:**

S MAIN COMPLAINT(s)

O ON EXAMINATION

Vital Signs:	**Height:** **Weight:**
BP:	Observations(unusual)
Temp:	
Pulse:	
Resp:	

A DIAGNOSIS (Medical)

(the **ICD code must match the written diagnosis**)

ICD-10 code:	**Written diagnosis:**

P CASE MANAGEMENT

(Remedy differentials, posology and motivation)

(Patient management plan)

Next Follow up appointment: (eg. 3weeks time) -

E PATIENT EDUCATION(Advice)

PRESCRIPTION

POWDERS	**CREAM / TISSUE SALTS**
Rx:	**Rx:**
Mitte:	**Mitte:**
Sig:	**Sig:**
Clinician's Auth:	**Clinician's Auth:**
VIALS	**DROPS/∅**
Rx:	**Rx:**
Mitte:	**Mitte:**
Sig:	**Sig:**
Clinician's Auth:	**Clinician's Auth:**

SIGNATURES

Clinicians Name:	**Students First Name:**
Clinicians Full Signature: **Date signed off:**	**Students Signature:**

Receptionist's signature:_____

Name of dispenser:	Date dispensed:

Appendix N: Pearson Chi-square test between the treatment and placebo group for both CARAT first and second visit

Table 1: carat first visit

		Almost every day	More than 2 days a week	1 or 2 a week	Never	Pearson Chi-square Test
Blood nose	Treatment	13.3	23.3	13.3	0.0	0.722
	Placebo	10.0	20.0	16.7	3.3	
Sneezing	Treatment	16.7	23.3	6.7	3.3	0.101
	Placebo	6.7	16.7	26.7	0.0	
Cough	Treatment	0.0	3.3	10.0	36.7	0.145
	Placebo	10.0	0.0	16.7	23.3	
Runny nose	Treatment	13.3	13.3	16.7	6.7	0.334
	Placebo	20.0	6.7	23.3	0.0	
Shortness of breath/dyspnoe	Treatment	0.0	0.0	3.3	46.7	0.368
	Placebo	3.3	0.0	0.0	46.7	
Wheezing in the chest	Treatment	0.0	0.0	0.0	50.0	
	Placebo	0.0	0.0	0.0	50.0	
Chest tightness upon physical excision	Treatment	0.0	0.0	0.0	50.0	
	Placebo	0.0	0.0	0.0	50.0	
Tiredness due to your allergic rhinitis	Treatment	0.0	26.7	23.3	0.0	0.057
	Placebo	16.7	16.7	13.3	3.3	
Wake up during the night because of your allergic rhinitis symptoms	Treatment	0.0	3.3	36.7	10.0	0.387
	Placebo	3.3	10.0	23.3	13.3	
In the last 4 weeks how many times did you have to increase the dose or frequency of medication due to your allergic rhinitis	Treatment	13.3	16.7	13.3	6.7	0.904
	Placebo	16.7	13.3	10.0	10.0	

Table 2: carat first visit

		Almost every day	More than 2 days a week	1 or 2 a week	Never	Pearson Chi-square Test
Blood nose	Treatment	10.0	6.7	16.7	23.3	0.833
	Placebo	6.7	3.3	23.3	23.3	
Sneezing	Treatment	0.0	13.3	26.7	10.0	0.091
	Placebo	0.0	0.0	40.0	10.0	
Cough	Treatment	0.0	0.0	6.7	43.3	0.539
	Placebo	3.3	3.3	6.7	36.7	
Runny nose	Treatment	6.7	10.0	20.0	13.3	0.974
	Placebo	6.7	10.0	23.3	46.7	
Shortness of breath/dyspnea	Treatment	0.0	0.0	3.3	46.7	0.759
	Placebo	0.0	0.0	3.3	46.7	
Wheezing in the chest	Treatment	0.0	0.0	3.3	46.7	0.500
	Placebo	0.0	0.0	0.0	50.0	
Chest tightness upon physical excision	Treatment	0.0	3.3	0.0	46.7	0.368
	Placebo	0.0	0.0	3.3	46.7	
Tiredness due to your allergic rhinitis	Treatment	0.0	6.7	26.7	16.7	0.341
	Placebo	0.0	0.0	9.0	20.0	
Wake up during the night because of your allergic rhinitis symptoms	Treatment	0.0	3.3	26.7	20.0	0.561
	Placebo	0.0	10.0	23.3	16.7	
In the last 4 weeks how many times did you have to increase the dose or frequency of medication due to your allergic rhinitis	Treatment	36.7	13.3	0.0	0.0	0.519
	Placebo	30.0	16.7	3.3	0.0	

APPENDIX O: PERMISSION TO CONDUCT RESSERCH AT DUT

Directorate for Research and Postgraduate Support
Durban University of Technology
Tromso Annexe, Steve Biko Campus
P.O. Box 1334, Durban 4000
Tel.: 031-3732576/7
Fax: 031-3732946
E-mail: ***moyos@dut.ac.za***

7th October 2016

Ms Thobile Tshabalala
c/o Department of Homoeopathy
Faculty of Health Sciences
Durban University of Technology

Dear Ms Tshabalala

PERMISSION TO CONDUCT RESEARCH AT THE DUT

Your email correspondence in respect of the above refers. I am pleased to inform you that the Institutional Research Committee (IRC) has granted full permission for you to conduct your research "The efficacy of a homoeopathic *Similasan Nasal Allergy Relief Spray*® in the management of allergic rhinitis in terms of the CARAT questionnaire" at the Durban University of Technology.

We would be grateful if a summary of your key research findings can be submitted to the IRC on completion of your studies.

Kindest regards.
Yours sincerely

_____
PROF. S. MOYO
DIRECTOR: RESEARCH AND POSTGRADUATE SUPPORT