Quality of life assessment in patients with Allergic Rhinitis at Universitas Hospital, Bloemfontein

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By

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i. Declaration

I, Dr D Ramdhani declare that the coursework Master's Degree mini-dissertation that I herewith submit is, in a publishable manuscript format for the Master's Degree qualification Otorhinolaryngology at the University of the Free State is my independent work, and that I have not previously submitted it for a qualification at another institution of higher education.

ii. Acknowledgement

I would like to express my gratitude to my supervisors Professor RY Seedat, Dr T Daniller, fellow colleagues, nursing staff, administrative clerk in the otorhinolaryngology department, for their contribution in making this study a success.

iii. Abstract

Introduction

Allergic rhinitis represents a global health problem that can adversely affect quality of life, impacting academic performance, social life and affecting work performance

Aims:

The aims of this study were to determine the impact of allergic rhinitis on the Quality of Life of adult patients attending the Ear Nose and Throat clinic at the Universitas Academic Hospital Complex and to determine the change in the Quality of Life of patients with allergic rhinitis after one month of treatment.

Methods

This was a prospective, descriptive study of patients over the age of 18 years who were diagnosed with allergic rhinitis at the Department of Otorhinolaryngology at Universitas Hospital between 1 May 2017 and 30 April 2018. Clinical data was recorded on a data form and the patients completed the Juniper mini Rhinoconjunctivitis Quality of life Questionnaire. Patients were reassessed after one month of treatment and again completed the Juniper mini Rhinoconjunctivitis Quality of life Questionnaire.

Results

85 patients were included in the study. Patients were aged 18 to 78 years of age with the mean of 37.86 years. There were 64.7% female and 35.3% males. 50% presented with moderate- severe intermittent disease, 44% with mild persistent disease, 4% with mild intermittent disease and 2% with moderate- severe persistent disease. There was a

significant improvement in quality of life following one month of treatment. The greatest improvements were in daily activities, nasal symptoms and eye symptoms.

Conclusion

Allergic rhinitis adversely affected quality of life, with a significant improvement in quality of life following one month of treatment.

iv. Abbreviations

AR: Allergic rhinitis

HRQOL: Health Related Quality of Life

IgE: Immunoglobulin E

MID: Minimal Important Difference

QOL: Quality of Life

RQLQ: Rhinoconjunctivitis Quality of Life Questionnaire

Chapter 1 – Literature Review

1.1. Introduction

Rhinitis is inflammation of the nasal mucosa (1). Allergic rhinitis (AR) is defined as a symptomatic disease of the nasal mucosa provoked by allergen exposure (2). This results from immunoglobulin E (IgE) mediated inflammation (2)(3).

The allergic immune response has an immediate and a late phase (3). Exposure to an allergen leads to sensitization. Thereafter antigen presenting cells (T lymphocytes) in the nasal mucosa are activated on subsequent allergen exposure. Interleukins are released with other cytokines which together drive the inflammatory process. Simultaneously mast cells, T and B-cells, macrophages and eosinophils infiltrate the nasal mucosa. T helper cells release cytokines that induce IgE formation (1). These IgE in turn stimulate the release of mediators such as histamine and leukotrienes responsible for the inflammatory process (1). The intermediate phase is characterized by mast cells coated with sensitized IgE which are activated by exposure to an allergen in the nasal mucosa. The mast cell degranulates and releases histamine, heparin, interleukins and other enzymes. This leads to oedema of nasal mucosal congestion of nasal sinusoids and stimulation of autonomic nerves. The late phase occurs 4 to 8 hours post allergen exposure. The late phase is thought to be driven by the chemical mediators from the mast cells. More inflammatory cells are attracted to the nasal mucosa and inflammatory mediators drive the inflammatory process. These cells include eosinophils, neutrophils, basophils, T lymphocytes and macrophages which become active and release inflammatory mediators (4). Platelet activating factor released from mast cells and also has a chemotactic effect for inflammatory cells implicated in the late phase of the allergic reaction (5). This results in rhinorrhoea, sneezing, nasal itching, and nasal obstruction. The nasal symptoms can be

accompanied by ocular allergic symptoms. Nasal symptoms (rhinorrhoea, sneezing, itchy nose, and nasal obstruction) may reverse spontaneously or with treatment (3).

The prevalence of AR is between 10 to 30 percent across the world (6). In Europe and the United States there are many epidemiological studies which show that in Europe the prevalence is between 23% - 30% and in the United States the prevalence is 12% - 30%. Studies from other parts of the world have a more diverse prevalence range (7). The postulated reason for this is the paucity of literature and the small cohorts. Larger cohorts are required to produce more accurate statistics. Available data shows a prevalence of 7 to 54% in Africa (3). Seedat et al (8) showed a prevalence rate of 39.1% in adult students in Bloemfontein. The prevalence of allergic disease is influenced by hygienic conditions, breast feeding and genetic predisposition. Urbanised areas have a higher prevalence of allergic diseases (9).

Air pollution from exhaust fumes and particulate matter have been associated with high rates of asthma and allergic airway disease. The offending agents noted from exhaust fumes include: ozone, nitrogen dioxide, and sulphur dioxide. Particulate matter includes: dust, carbon, metals, and inorganic and organic acids compounds (10). A systematic review had found that with both active and passive smoking there is an increase in allergic disease (11). It does this by altering the mucocilary function as well as causing an inflammatory reaction similar to that of an allergic reaction (11).

1.2 Clinical

The diagnosis of AR is based on clinical history and symptoms experienced by the patient (2). These symptoms can be classified into nasal symptoms which include: sneezing, nasal itching, rhinorrhoea, nasal congestion and obstruction as well as extra nasal symptoms: tearing, itching of the eyes and palate, conjunctival irritation and erythema, snoring and headache and sleep. Sleep is interrupted by poor breathing and lack of sleep causes irritability, fatigue, memory

deficits, daytime somnolence and impaired cognitive performance (2). The patients who suffer from AR experience difficulties with learning and are often excluded from social activities (3). Work productivity is also impaired. The socioeconomic status of patients is impacted because of the cost of treatment and the days of sick leave taken (2). These factors can significantly decrease ones quality of life (4).

The ARIA (Allergic Rhinitis and its Impact on Asthma) guideline was revised in 2016 and classifies AR depending on the duration of disease into intermittent or persistent and the severity of symptoms into mild or moderate to severe(7). Prior to this revision, AR was classified according to time and type of exposure into seasonal or persistent (6). Seasonal rhinitis is defined with a defined period when specific aeroallergens are in adbuance. Perennial rhinitis is defined by exposure to the allergen over a prolonged time (greater than eight months)(12). Studies have shown that despite extensive guidelines, and most recently the ARIA guidelines, general practitioners often misdiagnose the impact and severity of disease on a patient's quality of life. This leads to inappropriately treated disease and low patient satisfaction and in turn poor QOL. Patients may also not seek medical care because they may underestimate the impact of disease or manage it inadequately (2).

An American study showed that 37% of their patients had comorbid conditions that are frequently associated with AR and allergic disease. Asthma and AR have a strong relationship linked by similar epidemiological and pathophysiologic reactions (4). It has been said that 80% of patients with asthma have AR and AR control affects asthma control while 38% of AR patients have asthma (13). Allergic conjunctivitis is found in 52% of AR patients (14). Sleep disorders are associated with AR in a Spanish study (14). The other associations include skin rash (3%), cough and gastroesophageal reflux (14).

The ARIA guidelines recommend a treatment protocol which entails: patient education, allergen avoidance, pharmaceutical drugs and immunotherapy in a stepwise manner (13).

The ARIA guideline recommends that patients with persistent symptoms and moderate to severe symptoms use an intranasal corticosteroid, antihistamine or leukotriene receptor antagonist. The treatment recommendations for mild intermittent symptoms include: an oral antihistamine, intranasal antihistamine or decongestant or a leukotriene receptor antagonist in no preferred order. The addition of an intranasal corticosteroid or chromone (not in a preferred order is recommended) for the moderate to severe intermittent mild and the persistent mild group of patients (5).

The majority of AR cases are treated with pharmacological agents (2). The first-line pharmacotherapeutic treatment is intranasal steroids and/or antihistamines. Antihistamines are the most widely prescribed medications (2). The first generation antihistamines have the major disadvantage of sedation and anticholinergic effects. The second generation antihistamines are preferred because the side effect of sedation does not occur (2). Often antihistamine treatment is blamed for daytime sleepiness and fatigue (13). Antihistamines reduce nasal itching, sneezing and rhinorrhoea (1). Intranasal corticosteroids are also commonly prescribed to treat AR (2).

Studies have shown that intranasal steroids are effective in treating nasal obstruction. It has been demonstrated that if intranasal steroids are used regularly, nasal mucosa inflammation is reduced (1). Decongestants, mast cell stabilizers, and leukotriene receptor antagonists also form part of the arsenal to treat AR. Decongestants are alpha adrenergic agents however they cannot be used for prolonged periods of time because they have a rebound effect which causes drug-induced rhinitis. They are the most efficacious in relieving nasal obstruction (1,2). Oral decongestants do exist and do not have a rebound effect as with intranasal decongestants but

they produce systemic symptoms which result in insomnia and agitation. Leukotriene receptor antagonists are involved with inhibiting inflammatory mediators attaching to receptors. These have been shown to have an effect on daytime sleepiness, nasal itching and rhinorrhoea. Mast cell stabilizers have a similar mechanism of action to reduce inflammatory mediators. They functions as a mild anti-inflammatory agents(2). The table below summarises the effects of different drugs on nasal symptoms and amount effected by each agent (15).

Table I. Relative effectiveness of drugs on the symptoms of allergic rhinitis

	Nasal obstruction	Rhinorrhoea	Sneezing	Nasal itching
Intranasal corticosteroids	+++	+++	++	+
Antihistamines	+	+++	+++	+++
Intranasal cromones	+	+	+	+
Intranasal decongestants	++++	–	–	–
Anticholinergics	–	++	–	–
Leukotriene receptor antagonists	++	+	–	–

(From: Seedat RY. Treatment of allergic rhinitis: review article. Current Allergy Clin Immunol. 2013;26(1):11–6.)

1.3 AR effects on QOL

The symptoms of AR have a debilitating effect on patients' QOL (2,13). QOL refers to the subjective perception of wellbeing: emotional, physical, social and cultural aspects of an individual's life and all these aspects are affected by AR. In addition, the is a negative impact on the economy for both the patient and healthcare system. It impacts on sleep, daily activities, mental status and social functioning, irrespective of geographical location (3). Thompson quoted a large study which showed that as many as 90% of patients reported limitations when performing daily activities and work (4). The psychological effects experienced have also been investigated using the Positive Affect Negative Affect Scales by Marshall and Colon and showed significant decreases in scores in allergy season and impaired cognitive function (4).

Bousquet et al used the SF-36 in patients with AR and reported significant impairment in a number of domains in QOL when compared with the non-AR controls (4).

Extra-nasal symptoms are also a point of concern that can diminish the QOL, such as red eyes, itching and excessive tearing, mouth breathing, thirst, snoring and headache among a wide range of others (2,3). Patients feel irritable and exhausted when they have lack of sleep. The psychological effects on adults and children are different. Therefore, the need to evaluate adults and children differently is relevant and one tool cannot be used on adults and children. Adolescents have trouble concentrating, which affects their school performance. They also have impairment of sports activities. Children who are younger behave differently to both groups mentioned above; they have problems with having to take medications regularly and have discomfort with nasal obstruction (2).

1.3.1 Impact on sleep

Patients have a lack of sleep, which leads to irritability, fatigue, memory deficits, and daytime somnolence. These factors alone are a major factor in decreasing quality of life. Studies have shown that interrupted sleep and sleep deprivation can lead to increased daytime somnolence and impaired cognitive performance and have been linked to anxiety, depression and other psychiatric disease. In adolescents, sleep deprivation has been shown to lead to learning, behaviour, and attention problems (2).

1.3.2 Impact on learning and social life

Memory is fundamental for learning. Patients who have uncontrolled symptoms can suffer with memory loss. A study showed that the school going population were less affected by rhinorrhoea than by sleep deprivation. The same study showed that sleep deprivation was responsible for higher rates of absenteeism (2). Children feel isolated and this affects their social development. This is because with exposure to allergens (grass, pollen, animal dander)

they become sick and cannot participate in activities. This isolation is extended to school and family activities as to avoid contact with allergens. Allergen avoidance behaviour does not allow for unrestricted integration. Another study involving 1984 patients examined the influence of AR on social perspective. It was found that 70% felt embarrassment in social situations and 72% felt frustrated with practical problems (carrying around something to constantly wipe their nose, amongst others) (2).

1.3.3 Impact on productivity and socioeconomic impairment

The socioeconomic burden is classified into two types of costs: direct and indirect medical costs. Direct costs include: medical office visits, laboratory tests and medical management. In addition, these can be compounded if AR is associated with asthma, atopic dermatitis, allergic conjunctivitis, frequent upper respiratory tract infection and nasal polyps or a need for surgery. Indirect costs are those seen as a result of loss of productivity and absenteeism. Some American studies show estimated that 50% of patients with AR at some point contribute to loss of productivity and have experienced loss of jobs as a result. Indirect costs are estimated at 4 billion US dollars per year. Patients need to deal with these costs and live with long term burden of disease (change in daily activities to avoid allergens) (2).

1.4 Measurement of QOL

The development of quality of life assessment in AR started to develop in the 1980's (8). It is widely accepted that QOL measurement is recommended in protocols (ARIA, EPOS) for the assessment of QOL in AR (15). The ARIA classification is based on duration and severity which are grouped into four classes (16). Health-related quality of life (HRQOL) is defined as the subjective perception of the impact that their disease has on their life (17). HRQOL measurement depends on the instrument that is used to gather data. HRQOL instruments are classified into two groups: generic and disease specific. Generic instruments are used to gather

information about the general health measures of well-being of the patient. It can be used for any disease, intervention, clinical trials and populations groups. A number of generic tools are available for AR. The advantage of generic scales is that they can provide information about unexpected HQOL and that it can be used to compare different diseases. The disadvantage of the use of generic tools is that they are nonspecific and will miss major disease specific elements and cannot pick up small clinically meaningful changes. Some examples of these include: The Sickness impact profile, Study 36-Item Short Form Health Survey (SF-36). The SF-36 is very commonly used and consists of 36 questions in nine domains. Disease specific tools were developed to overcome these disadvantages and are designed to target specific functional problems and diseases. The disadvantage is that information cannot be compared to other illnesses. Generic instruments can also be modified to measure specific disease outcomes. The work productivity impairment instrument has been used in AR at work and schools. The most frequently cited tool used in AR is the Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) (4).

1.5 Mini Rhinoconjunctivitis Quality of Life Questionnaire

The Mini Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) is based on the Rhinoconjuncitivitis QOL questionnaire. The RQLQ was shortened using recognized procedures for shortening QOL questionnaires. The purposed use for this questionnaire was to be used for large clinical trials/cohorts as time in filling in the questionnaire was taken into account (12). It consists of a 28-item list in health-related domains (practical problems, nasal symptoms, eye symptoms, sleep activities, emotional function) (4). This is a well-developed and validated questionnaire in a number of countries. It has been translated into 16 languages (18). It has been used in Brazil, Canada, Columbia, USA, Europe and Iran (3,18). The questionnaire was developed by Juniper et al (16). It is used to measure functional problems which patients experience. It has been fully validated and can be used to gather strong

measurement outcomes and has a high level of evaluative and discriminative properties (18). In a systematic review it was found that the HRQOL is used with other measuring scales visual analogue scale, Epworth sleepiness scale and asthma related tools (3).

1.6 Conclusion

AR is not a life-threatening disease. Research shows that AR symptoms have a debilitating effect on psychological, emotional, physical, financial aspects of life (4). AR is a chronic disease and is characterised by episodes of worsening symptoms on exposure to allergens and this is reversible spontaneously or with treatment. The development of QOL tools helped to gain knowledge and understanding of the impact on QOL was found. The cost of treating these, impacts on the socioeconomic status of patients and the economy (2). There is a scarcity of literature available on quality of life studies relating to AR in Africa. South African literature is limited on the effects of allergic rhinitis on the quality of life and is further research is warranted (8)

Chapter 2 – Publishable Article

Quality of life assessment in patients with Allergic Rhinitis

at

Universitas Hospital, Bloemfontein

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2.1 Abstract

Introduction

Allergic rhinitis represents a global health problem that can adversely affect quality of life, impacting academic performance, social life and affecting work performance.

Aims:

The aims of this study were to determine the impact of allergic rhinitis on the Quality of Life of adult patients attending the Ear Nose and Throat clinic at the Universitas Academic Hospital Complex and to determine the change in the Quality of Life of patients with allergic rhinitis

after one month of treatment instituted at Ear Nose and Throat clinic at the Universitas Academic Hospital Complex.

Methods

This was a prospective, descriptive study of patients over the age of 18 years who were diagnosed with allergic rhinitis at the Department of Otorhinolaryngology at Universitas Hospital between 1 May 2017 and 30 April 2018. Clinical data was recorded on a data form and the patients completed the Juniper mini Rhinoconjunctivitis Quality of life Questionnaire. Patients were reassessed after one month of treatment and again completed the Juniper mini Rhinoconjunctivitis Quality of life Questionnaire.

Results

Fifty patients were included in the study. Patients were aged 18 to 78 years of age with the mean of 37.9 years. There were 35/70% female and 15/30% males. 50% presented with moderate- severe intermittent disease, 44% with mild persistent disease, 4% with mild intermittent disease and 2% with moderate- severe persistent disease. There was a significant improvement in quality of life following one month of treatment. The greatest improvements were in daily activities, nasal symptoms and eye symptoms.

Conclusion

Allergic rhinitis adversely affected quality of life, with a significant improvement in quality of life following one month of treatment.

2.2 Introduction

Allergic rhinitis (AR) is defined as a symptomatic disease of the nasal passages and paranasal sinuses. As a result of immunoglobulin E (IgE) mediated inflammation after exposure of the mucosa to the specific allergen (2)(3). AR is a chronic disease with intermittent acute episodes (19). The prevalence of AR is between 10 to 30% across the world (3). Available data shows a prevalence of 7 to 54% in Africa (3). `

The diagnosis of AR is based on the clinical history and symptoms (2). These symptoms can be classified into nasal symptoms which include: sneezing, nasal itching, rhinorrhoea, nasal congestion and obstruction as well as extra-nasal symptoms: tearing, itching of the eyes and palate, conjunctival irritation and erythema, snoring, headache and sleep. Lack of adequate sleep leads to irritability, fatigue, memory deficits, daytime somnolence and impaired cognitive performance (2). Patients who suffer from AR experience difficulties with learning and are often excluded from social activities (3). Work productivity is also impaired. The socioeconomic status of patients is impacted because of the cost of treatment and the days of sick leave (2). These factors can significantly decrease quality of life (4).

Quality of life can be broadly defined as the aspects of life that give subjective satisfaction (20). Patients perception is variable and influenced by many aspects of life (cultural, geographical, financial etc.) therefore assessment tools for QOL are recommend in various guidelines (ARIA, EPOS) for the of QOL in AR (15). The ARIA classification is based on duration and severity which are grouped into four categories. Baiardini et al. had investigated QOL and found that QOL was lower in all four of the ARIA classified patients when compared to control group. This study also identified that severity of AR had a bigger impact on QOL when compared to the duration of illness (16).

Health-related quality of life (HRQOL) is defined as the subjective perception of patients of the impact that their disease has on their life(17). HRQOL instruments include generic instruments, the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36) and Kidscreen-27 (21)(4). These have the disadvantage that they are not specific.

Disease-specific instruments provide intricate information about the disease. The Rhinitis Symptom Utility Index is an example of a disease - specific tool that uses a rhinitis specific questionnaire (22). The Mini Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) is based on the Rhinoconjuncitivitis QOL questionnaire. The RQLQ was shortened using recognized procedures for shortening QOL questionnaires. The purposed use for this questionnaire was to be used for large clinical trials/cohorts as time in filling in the questionnaire was taken into account (18). It consists of a 28 item list in health related domains (practical problems, nasal symptoms, eye symptoms, sleep activities, emotional function) (4). This is a well-developed and validated questionnaire in a number of countries and it has been translated into 16 languages (18). It has been used in Brazil, Canada, Columbia, USA, Europe, Iran (2)(18). The questionnaire was developed by Juniper et al (7). It is used to measure functional problems which patients experience. It has been fully validated and can be used to gather strong measurement outcomes and has a high level of evaluative and discriminative properties (18). In a systematic review it was found that the HQROL is often used with other measuring scales visual analogue scale, Epworth sleepiness scale and asthma related tools (3).

There are gaps in the literature available on QOL studies relating to AR outside of America and Europe. Further investigation on the quality of life in patients with AR has become popular and investigation is warranted (2).

2.3 Aim

The aims of this study were to determine the impact of allergic rhinitis on the Quality of Life of adult patients attending the Ear Nose and Throat clinic at the Universitas Academic Hospital Complex and to determine the change in the Quality of Life of patients with allergic rhinitis after one month of treatment instituted at Ear Nose and Throat clinic at the Universitas Academic Hospital Complex.

2.4 Material and methods

This was a prospective, descriptive study of adult patients (over the age of 18 years) that presented to the Department of Otorhinolaryngology at Universitas Hospital between 1 May 2017 and 30 April 2018 that were newly diagnosed with allergic rhinitis. Clinical data was recorded on a data form and the patients completed the mini RQLQ at initial presentation and at the follow up visit after one month. Written informed consent was obtained from all patients. The study was submitted and approved by the Health Sciences Research Ethics Committee of the University of the Free State (HSREC 51/2017) and Free State Department of Health (FS_2017RP52_91).

The following information was also documented:

- Date of birth
- Date of first clinic visit
- Gender
- Main presenting symptom/s
- Current medication use
- Compliance to medication use
- Comorbid diseases: asthma, eczema, food allergies
- Residential area
- Aggravating or improving factors and seasons
- Pets, underfloor heating and humidifier use
- Skin prick test results if done
- Treatment received

Treatment that was offered patients were in accordance to the ARIA guidelines.

A pilot study was performed using the first 10 patients which were included in the study. Descriptive statistics, namely frequencies and percentages for categorical data, and medians for numerical data, were calculated. Associations were determined using Fisher's exact test.

2.5 Results:

2.5.1 Demographics

A total of 85 patients were included in the study. The mean age of the patients was 37.9 years (range 18-77 years). There were 30 males (35.3%) and 55 females (64.7%). It was found that 76 (89.4%) live in an urban area and 9 (10.6%) live in a rural area.

The largest group of patients 29 (34.1%) of patients were from Bloemfontein and 19 (22.4%) patients were from Thabanchu. The rest of the patient came from surrounding areas of the Free State.

The severity of the disease was classified according to the ARIA classification (**Table 1**).

Table 1 – Classification of disease

Classification of disease	**% (n = 85)**
Mild Intermittent	3.6 (n = 3)
Mild persistent	42.4 (n = 36)
Moderate severe-intermittent	51.8 (n = 44)
Moderate severe-persistent	2.6 (n = 2)

None of the patients had food allergies; 30.6% had asthma and 7.1% had eczema.

It was found that 36 (42.4%) of the participants were on treatment for allergic rhinitis at the time of their first visit to the ENT clinic, while 49 (57.7%) were not on treatment. All 36 (100%) participants were on intranasal steroids, 8 (22.2%) were on an oral histamine and 9 (25%) used a topical decongestant.

Sixty patients (70.6%) had never lived at the coast and the remaining 25 (29.4%) had a history of living at the coast. Symptoms were worse in the spring for 39 (45.9%) of patients, in the autumn for 22 (25.9%), in the summer for 17 (20%) and in the winter for 7 (8.2%).

The results of skin prick testing are shown in **Table 2**.

Table 2 – Skin prick test results

Allergen	**% (n = 85)**
Cynodon dactylon (Bermuda grass)	69,4 (n = 59)
Zea mays (Maize pollen)	67 (n = 57)
Lolium perenne (Rye grass)	58,8 (n = 50)
Alternaria alternatae	38,8 (n = 33)
D.pteronyssinus	36,5 (n = 31)
Feathers	24,7 (n = 21)
B. germanica	20 (n = 17)
Aspergillus fumigatus	16,5 (n = 14)
Dog epithelia	15,3 (n = 13)

Cat epithelia	9,4 (n = 8)

Dust was identified as an aggravating factor in 32 (37.7%) of the patients. 14 (16.5%) noted that air conditioning had aggravated their symptoms, 9 (10.6%) identified cold, 2 (2.35%) cheese and 1 (1.2%) chemicals. The remaining 27 (31.8%) did not know what aggravated their symptoms.

2.5.2 Quality of life questionnaire results

The mean scores pre and post treatment for each individual are shown in table 3.

Table 3 – Table showing the pre and post treatment scores for all of the questions

Question	Pre-Treatment Mean Score (Range)	Post-Treatment Mean Score (Range)
1. Regular activities at home and at work	3 (1- 5)	2 (0 – 5)
2. Recreational activities	3 (0- 5)	2 (0- 5)
3. Sleep	3 (0- 6)	2 (0- 5)
4. Need to rub nose/eyes	2 (0- 5)	1 (0- 3)
5. Need to blow nose repeatedly	2 (0- 6)	1 (0- 3)
6. Sneezing	2 (0- 5)	1 (0- 5)
7. Blocked nose	4 (0- 6)	2 (0- 5)

8. Runny nose	2 (0- 6)	0 (0- 4)
9. Itchy eyes	2 (0- 5)	0 (0- 3)
10. Sore eyes	0 (0- 5)	0 (0- 2)
11. Watery eyes	2 (0- 5)	0 (0- 5)
12. Tiredness and/or fatigue	2 (0- 6)	0 (0- 5)
13. Thirst	0 (0- 5)	0 (0- 5)
14. Feeling irritable	0 (0- 5)	0 (0- 4)
15. Coughing	1 (0-5)	0 (0- 2)
16. Waking up between 1 – 5 am with: headaches, dizziness, stomach cramp, bloating or dry cough	0 (0- 6)	0 (0- 5)
17. Itching of the skin on the roof of mouth	0 (0- 3)	0 (1- 3)
18. Rashes/hives	0 (0- 3)	0 (0)
19. Swelling of ankels, feet, hands and face	0 (0- 2)	0 (0- 1)
20. Excessive chills with sudden temperature change	0 (0- 2)	0 (0- 2)

21. Headaches/ migraines	1 (0- 3)	0 (0- 3)
22. Blenching/ bloating	0 (0- 1)	0 (0- 3)
23. Constipation or diarrhea	0 (0- 2)	0 (0- 1)

Table 4 – Table showing median scores pre- and post-treatment

Question Group	**Median score pre-treatment (Lower quartile – upper quartile)**	**Median score post-treatment (Lower quartile – upper quartile**	**Median difference**
Activities	10 (7 – 11)	5 (3 – 7)	-3
Practical problems	4 (2 – 6)	2 (1 – 3)	-2
Nasal symptoms	8 (6 – 11)	4 (2 – 5)	-4
Eye symptoms	4 (2 – 6)	0 (0 – 2)	-3
Other	4 (2 – 6)	0 (0 – 1)	-3

The quality of life scores and change after one month of treatment are shown in Table 4.

This table shows a summary of the median scores of patients for the 5 domains respectively. Patients were most troubled with nasal symptoms (median score 8) and activities were impaired (median score 10). No statistical significance between both groups.

Table 5 -Table showing mean score for activities

Activities	**Mean Pre-treatment score (Range)**	**Mean Post-treatment score (Range)**
Activities at home	3 (1 – 5)	2 (0 – 5)
Recreational activities	3 (0 – 5)	2 (0 – 5)
Sleeping	3 (0 – 6)	2 (0 – 5)
p value	>0,21	

Table 6 -Table showing mean score for nasal symptoms

Nasal symptoms	Mean Pre-treatment score	Mean Post-treatment score
Blocked nose	4 (0 – 5)	2 (0 – 3)
Sneezing	2 (0 – 6)	1 (0 – 3)
Runny nose	2 (0 – 5)	0 (0 – 5)
p vale	>0,94	

In the group nasal symptoms, blocked nose was the most troubling; 87% scored >3 compared to runny nose 34.3% and sneezing 47.1%. The p value indicates no statistically significance between both groups.

Good compliance rates were documented with 75.3% (64) of the participants that were compliant and 24.7% (21) were not compliant.

The quality of life of all patients had improved, both those that were compliant and those that were not compliant with medication. A p > 0.36 which is statically significant.

2.6 Discussion

HRQOL is a standard of care in AR, and is used to monitor treatment response (17). This study found that AR affected the QOL of the patients at Universitas Hospital. This is in keeping with other studies which showed that QOL was significantly affected in patients diagnosed with AR (19). A similar result was obtained by Green and colleagues designed a study to screen AR and

its impact on QOL. It was conducted in the 5 major cities in South Africa and showed that 85.2% had the feeling of being miserable. In an Austrian study by Sharp and Seeto an online questionnaire demonstrated that 97% of the participants' mood was affected negatively and AR adversely affected their relationships in 82% of patients (3). A Colombian study used the Kidscreen – 27 and the SF-36 to assess emotional performance and psychological wellbeing, and found that subjects with and without asthma had reduced psychological well-being in both adults and children. This study also showed that patients with AR had limitations with physical activities that was worse in patients with AR and asthma (21). This study also highlighted that treatment of AR resulted in improvement of QOL. Camelo et al (2) in their study showed that the use of prophylactic measures and pharmaceutical agents results in improve of QOL. This has been demonstrated by many studies: appropriate treatment reduces symptoms of AR and thereby improves QOL (3).

The symptoms of AR have a debilitating effect on patients' QOL. QOL refers to the subjective perception of wellbeing: emotional, physical, social and cultural aspects of an individual's life. In addition, economically, it burdens the patient and the healthcare system. It impacts on sleep, daily activities, mental status and social functioning, irrespective of geographical locations (3). It is also important to take note that physical and emotional impairment affects adults and children in different ways. It was found that patients feel inconvenienced by a blocked and runny nose and sneezing. They also experience practical problems, for example having to carry around tissues. Their physical limitations can cause anxiety and frustration. Patients are also felt irritable from lack of sleep. Children do not have as many physical limitations when compared to adults. Children experience more emotional impairments. School-going children have significant impairment with learning and concentration (2). AR is a chronic illness and requires treatment for long periods of time. This poses an economic burden in the long term.

The other factors that are involved in poor QOL include comorbidities and their treatment which increases economic burden (2).

There was a slight female predominance in this study (64.7%) in keeping with studies in Nigeria (19), and Spain (21). The median age in this study was 35 years in keeping with other studies that demonstrates younger predominance (23). In this study, the ARIA classification of patients was used. The mild persistent group was 42,4% and the moderate severe-intermittent group was 51,8% (Table. 1). This implies that the QOL is expected to be poor as severity of disease is an indicator of negative QOL (15). A study done in Iran had also used the ARIA guidelines to classify their patients and the results obtained showed 73% either moderate - severe intermittent or moderate - severe persistent AR. It also showed that 30.6% of the participants had asthma and 7.1% had eczema and no food allergies were reported. This finding did not correlate with other studies which showed that 38% of patients with AR have asthma and a range of 40 – 80% of other allergic illnesses associated with AR (8)(1).Asthma does not seem to worsen the QOL, but treatment of AR reduces the severity and incidence of asthma (19).

Treatment strategies involve: patient education allergen avoidance, pharmacological agents and immunotherapy. Allergen avoidance is thought to be the first line of treatment however avoidance techniques are impractical and almost impossible to adhere to. In the majority of AR cases, pharmacological agents are the mainstay of treatment (2).

The ARIA guidelines treatment protocol recommend oral antihistamines, intranasal steroids, local decongestion for less than 10 days, local chromone, immunotherapy and other drugs and is based on treatment in a stepwise manner (13). In this study 36 (42.2%) of the participants were on treatment prior to being seen by a specialist. All of these 36 patients were on intranasal steroids, 9 patients on nasal decongestants and 8 patients on oral antihistamines. Long-term

treatment with decongestants is not recommended for AR (9). Green and colleagues noted that 63.1% of patients were compliant with treatment (24). The reason for this is multifactorial and ranges from: time, side effects, understanding and replicating correct techniques and availability of medication.

The most common aggravating factors that were identified was dust (37.7%), and then followed by air conditioner, cold weather, cheese and chemicals. Symptoms were overall, worst in spring and symptoms better in winter. This is in keeping with a similar study done by Seedat et al showed that AR symptoms were worse in the month of spring (8). A South African study identified these triggering factors: smoky atmosphere (27.7%), air pollution (23.9%) and changes in weather (27.3%) (5). In Australia it was also found that the most troubling season is spring (25).

Skin prick tests were performed on all patients included in the study. The most common allergens identified was Bermuda grass (69.4%), maize pollen (67%), rye grass (58.8%), Alternaria alternata (38.8%), house dust mite (36.5%), feathers (24.7%), B. germancia (20%), Aspergillus fumigatus (16.5%), dog epithelia (15.3%) and cat epithelia (9.4%).

The Free State province has a high levels of maize pollen, eucalyptus pollen and grass pollen (26). It has been demonstrated that 67% of the patients in this study have positive skin prick test to maize pollen thus it would be very difficult to control allergen exposure in this environment.

The Free State province has a high concentration of maize pollen, eucalyptus and grass pollens (26). It has been demonstrated that 67% of the patients in this study have positive skin prick test to maize pollen thus it would be very difficult to control allergen exposure in this environment.

In this study when the pre- and post-treatment scores were compared it had shown that there was an overall improvement in all the groups post-treatment. Based on the frequency of AR symptoms, we found that the most prevalent symptom in patients was nasal congestion and rhinorrhoea. The most prevalent symptom reported in American patients was nasal congestion. It is indicated a 90% prevalence rate of nasal congestion and in the same study that 92% found nasal congestion attributing to poor QOL (23). It is said that any treatment that improves nasal symptoms will improve QOL (2).

2.7 Conclusion:

This study has demonstrated that symptoms of AR and the accompanying allergic conditions impact negatively on the quality of life and on sleep, daily activities, physical activities, mental status and social functioning. Treatment of AR can result in an improvement in affected patients' quality of life. The improvement is due to a decrease in nasal congestion which is the most troubling symptom amongst others. There is an international consensus that HRQOL tools should be used as standard of practice (17). South African literature is limited on the effects of allergic rhinitis on the quality of life and further research is warranted (8).

2.8 Limitations

Data collection could have extended on gathering information about: smoking and its effects on AR, technique of using nasal spray. Compliance could have been looked at in more details. Treatment methods and exact modalities per patient could have been recorded and discussed.

2.9 Recommendations

Further studies on the adult population should be done with relation to AR given the paucily of information for Sub-Saharan Africa. The recommendation would be on prevelance, compliance to treatment, region specific allergens and can address all aspects of QOL and AR.

2.8 References

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Appendices

Appendix A – English MiniRQLQ

MINI RHINOCONJUNCTIVITIS QUALITY OF LIFE QUESTIONNAIRE (MiniRQLQ)

QUESTIONNAIRE TO BE COMPLETED BY THE PATIENT (SELF-ADMINISTERED) ENGLISH VERSION FOR SOUTH AFRICA

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Translated by MAPI INSTITUTE
Senior Translator: Wendy Lochner

DECEMBER 2012

MINI RHINOCONJUNCTIVITIS QUALITY OF LIFE QUESTIONNAIRE
(ENGLISH VERSION FOR SOUTH AFRICA)
QUESTIONNAIRE TO BE COMPLETED BY THE PATIENT

PATIENT No.: _____

DATE: _____

Please complete **all** questions by circling the number that best describes how **troubled** you have been during **the past 7 days as a result of your nose/eye symptoms**.

	Not troubled	Hardly troubled at all	Somewhat troubled	Moderately troubled	Quite troubled	Very troubled	Extremely troubled
ACTIVITIES							
1. REGULAR ACTIVITIES AT HOME AND AT WORK (your occupation or tasks that you have to do regularly inside and outside your home and/or garden)	0	1	2	3	4	5	6
2. RECREATIONAL ACTIVITIES (indoor and outdoor activities with friends and family, sports, social activities, hobbies)	0	1	2	3	4	5	6
3. SLEEP (difficulties getting a good night's sleep and/or falling asleep at night)	0	1	2	3	4	5	6
PRACTICAL PROBLEMS							
4. NEED TO RUB NOSE/EYES	0	1	2	3	4	5	6
5. NEED TO BLOW NOSE REPEATEDLY	0	1	2	3	4	5	6

MINI RHINOCONJUNCTIVITIS QUALITY OF LIFE QUESTIONNAIRE
(ENGLISH VERSION FOR SOUTH AFRICA)
QUESTIONNAIRE TO BE COMPLETED BY THE PATIENT

PATIENT No.: _____

DATE: _____

How **troubled** have you been during the **past 7 days** as a result of these symptoms?

	Not troubled	Hardly troubled at all	Somewhat troubled	Moderately troubled	Quite troubled	Very troubled	Extremely troubled
NASAL SYMPTOMS							
6. SNEEZING	0	1	2	3	4	5	6
7. BLOCKED NOSE	0	1	2	3	4	5	6
8. RUNNY NOSE	0	1	2	3	4	5	6
EYE SYMPTOMS							
9. ITCHY EYES	0	1	2	3	4	5	6
10. SORE EYES	0	1	2	3	4	5	6
11. WATERY EYES	0	1	2	3	4	5	6
OTHER SYMPTOMS							
12. TIREDNESS (NEEDING SLEEP) AND/OR FATIGUE (LACK OF ENERGY)	0	1	2	3	4	5	6
13. THIRST	0	1	2	3	4	5	6
14. FEELING IRRITABLE	0	1	2	3	4	5	6

How **troubled** have you been during the **last week** as a result of these symptoms?

		Not troubled	Hardly troubled at all	Somewhat troubled	Moderately troubled	Quite a bit troubled	Very troubled	Extremely troubled
16	Waking up between the hours of 1-5 am with: headaches, dizziness, stomach cramps, bloating or dry cough	0	1	2	3	4	5	6
17	Itching of the skin or roof of mouth	0	1	2	3	4	5	6
18	Rashes/hives	0	1	2	3	4	5	6
19	Swelling of ankles, feet, hands or face	0	1	2	3	4	5	6
20	Excessive chills with sudden temperature change	0	1	2	3	4	5	6
21	Headaches/Migraines	0	1	2	3	4	5	6
22	Belching/Bloating	0	1	2	3	4	5	6
23	Constipation or Diarrhea	0	1	2	3	4	5	6

Appendix B – Afrikaans MiniRQLQ

MINI-RINOKONJUNKTIVITIS VRAELYS OOR LEWENSKWALITEIT (MiniRQLQ)

SELF TOEGEDIEN
(SELF-ADMINISTERED)
AFRIKAANS VERSION FOR SOUTH AFRICA

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Translated by MAPI INSTITUTE

AUGUSTUS 2012

MINI-RINOKONJUNKTIVITIS VRAELYS OOR LEWENSKWALITEIT
(AFRIKAANS VERSION FOR SOUTH AFRICA)
SELF TOEGEDIEN

PASIËNT ID _____

DATUM: _____

Voltooi asseblief **al** die vrae deur die getal te omkring wat die beste beskryf hoe **gepla** u was gedurende die **laaste week as gevolg van u neus-/oogsimptome**.

	Nie gepla nie	Nouliks gepla	Ietwat gepla	Matig gepla	Heelwat gepla	Baie gepla	Uiters gepla
AKTIWITEITE							
1. GEREELDE AKTIWITEITE BY DIE HUIS EN BY DIE WERK (u beroep of take wat u gereeld by u huis en/of tuin moet doen)	0	1	2	3	4	5	6
2. ONTSPANNINGSAKTIWITEITE (binnens- en buitenshuise aktiwiteite saam met vriende en familie, sport, sosiale aktiwiteite, stokperdjies)	0	1	2	3	4	5	6
3. SLAAP (moeite om 'n goeie nag se slaap te kry en/of om in die aand aan die slaap te raak)	0	1	2	3	4	5	6
PRAKTIESE PROBLEME							
4. BEHOEFTE OM NEUS/OË TE VRYF	0	1	2	3	4	5	6
5. BEHOEFTE OM HERHAALDELIK NEUS UIT TE SNUIT	0	1	2	3	4	5	6

MINI-RINOKONJUNKTIVITIS VRAELYS OOR LEWENSKWALITEIT
(AFRIKAANS VERSION FOR SOUTH AFRICA)
SELF TOEGEDIEN

PASIËNT ID _____

DATUM: _____

Hoe **gepla** was u gedurende die **laaste week** deur hierdie probleme as gevolg van u neus-/oogsimptome?

	Nie gepla nie	Nouliks gepla	Ietwat gepla	Matig gepla	Heelwat gepla	Baie gepla	Uiters gepla
NEUSSIMPTOME							
6. NIES	0	1	2	3	4	5	6
7. VERSTOPTE/TOE NEUS	0	1	2	3	4	5	6
8. LOOPNEUS	0	1	2	3	4	5	6
OOGSIMPTOME							
9. JEUKERIGE OË	0	1	2	3	4	5	6
10. SEER OË	0	1	2	3	4	5	6
11. WATERIGE OË	0	1	2	3	4	5	6
ANDER SIMPTOME							
12. TAMHEID EN/OF MOEGHEID	0	1	2	3	4	5	6
13. DORS	0	1	2	3	4	5	6
14. VOEL PRIKKELBAAR	0	1	2	3	4	5	6

MiniRQLQ - South Africa/Afrikaans - Version of 03 Aug 12 - MAPI Institute.
ID6838 / MiniRQLQ _AU1.0_afr-ZA.doc

Appendix C – Demographic information

Patient No.: _____ | | 1-2

File No.: _____

Date:(d/m/y) _____ | | | | | | | | | 3-10

Date of birth:(d/m/y) _____ | | | | | | | | | 11-18

Gender:(M/F) _____ | 19

Closest town/city:_____ | | 20-21

Urban/Rural (U/R)_____ | 22

Farm resident:Yes/No | 23

Symptoms (prior to treatment)

Nasal obstruction | 24

Rhinorrhoea | 25

Post-nasal drip [ ] 26

Sneezing [ ] 27

Nasal itching [ ] 28

Classification:_____ [ ]

Mild intermittent (1), mild persistent (2), Moderate-severe intermittent

(3), M-S persistent (4) 29

Asthma: Yes/No [ ] 30

Eczema: Yes/No [ ] 31

Allergic conjunctivitis: Yes/No [ ] 32

Previously lived at coast:Yes/No [ ] 33

Ever been to coast:Yes/No [ ] 34

Occupation:_____ [ ][ ] 1-2

Symptoms worse at work:Yes/No [ ] 3

Symptoms better when away from work:Yes/No [ ]

4

Symptoms worse at home:Yes/No ☐ 5

Symptoms better when away from home:Yes/No ☐ 6

Aggravating factors:_____ ☐☐ 7-8

_____ ☐☐ 9-10

_____ ☐☐ 11-12

Dogs at home: Yes/No ☐ 13

Cats at home: Yes/No ☐ 14

Carpets in home:Yes/No ☐ 15

Underfloor heating:Yes/No ☐ 16

Use of humidifier:Never (1), Occasionaly (2) Monthly (3), Weekly (4), Daily (5) ☐ 17

Exposure to wheat:Yes/No	Previous	Current		
In field	_____	_____	☐	☐

			18	19
Store	_____	_____	☐	☐
			20	21
Mill	_____	_____	☐	☐
			22	23
Flour	_____	_____	☐	☐
			24	25

Exposure to maize:Yes/No

In field	_____	_____	☐	☐
			26	27
Store	_____	_____	☐	☐
			28	29
Mill	_____	_____	☐	☐
			30	31

Symptoms worse in: (Yes/No)

Spring	_____	☐
		32
Summer	_____	☐
		33
Autumn	_____	☐
		34
Winter	_____	☐
		35

Symptoms better in: (Yes/No)

Spring _____ ☐ 36

Summer _____ ☐ 37

Autumn _____ ☐ 38

Winter _____ ☐ 39

SPT results:	**Wheal (mm)**	**Flare (mm)**		
D.pterynosinnus	_____	_____	☐☐ 1-2	☐☐ 3-4
D. farinae	_____	_____	☐☐ 5-6	☐☐ 7-8
G. domesticus	_____	_____	☐☐ 9-10	☐☐ 11-12
L. destructor	_____	_____	☐☐ 13-14	☐☐ 15-16
B. tropicalis	_____	_____	☐☐ 17-18	☐☐ 19-20
A. siro	_____	_____	☐☐	☐☐

			21-22	23-24
T. putrescentiae	_____	_____		
			25-26	27-28
B. germanica	_____	_____		
			29-30	31-32
Cynodon dactylon (Bermuda grass)	_____	_____		
			33-34	35-36
Lolium perenne (Rye grass)	_____	_____		
			37-38	39-40
Zea mays (Maize pollen)	_____	_____		
			41-42	43-44
Platanus acerifol (London Plane tree)	_____	_____		
			45-46	47-48
Alternaria alternata	_____	_____		
			49-50	51-52
Aspergillus fumigatus	_____	_____		

			53-54	55-56
Cat epithelia	_____	_____	☐☐	☐☐
			57-58	59-60
Dog epithelia	_____	_____	☐☐	☐☐
			61-62	63-64
Feathers	_____	_____	☐☐	☐☐
			65-66	67-68
Histamine	_____	_____	☐☐	☐☐
			69-70	71-72
Saline	_____	_____	☐☐	☐☐
			73-74	75-76
Total IgE	_____		☐☐☐☐ 1-4	☐☐ 5-6
ImmunoCAP RAST results	**kU/l**	**Grade**		
D.pterynosinnus	_____	_____	☐☐☐ 7-9	☐☐ 10-11 ☐ 12
D. farinae	_____	_____	☐☐☐	☐☐ ☐

				16-	
			13-15	17	18
B. tropicalis	_____	_____			
				22-	
			19-21	23	24
A. siro	_____	_____			
				28-	
			25-27	29	30
L. destructor	_____	_____			
				34-	
			31-33	35	36
T. putrescentiae	_____	_____			
				40-	
			37-39	41	42
G. domesticus	_____	_____			
				46-	
			43-45	47	48
B. germanica	_____	_____			
				52-	
			49-51	53	54
P. americana	_____	_____			
				58-	
			55-57	59	60
B. orientalis	_____	_____			

				64-	
			61-63	65	66
Spidermite	_____	_____			
				70-	
			67-69	71	72

Appendix D – Consent

CONSENT TO PARTICIPATE IN RESEARCH

PROJECT TITLE: Quality of life assessment in patients with Allergic Rhinitis

You have been asked to participate in a research study.

You have been informed about the study
by_____

You may contact Dr D Ramdhani at 051 4053344 any time if you have questions about the research.

You may contact the Secretariat of the Ethics Committee of the Faculty of Health Sciences, UFS at telephone number (051) 4052812 if you have questions about your rights as a research subject.

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to terminate participation.

If you agree to participate, you will be given a signed copy of this document as well as the participant information sheet, which is a written summary of the research.

The research study, including the above information has been verbally described to me.
I understand what my involvement in the study means and I voluntarily agree to participate.

_____ _____
Signature of Participant **Date**

_____ _____
Signature of Witness **Date**
(Where applicable)

_____ _____
Signature of Translator **Date**
(Where applicable)

Appendix E – Ethics Approval

UNIVERSITY OF THE FREE STATE
UFS-UV
HEALTH SCIENCES

IRB nr 00006240
REC Reference nr 230408-011
IORG0005187
FWA00012784

30 August 2017

DR DEVESH RAMDHANI
DEPT OF OTORHINOLARYNGOLOGY
FACULTY OF HEALTH SCIENCES
UFS

Dear Dr Devesh Ramdhani

HSREC 51/2017 (UFS-HSD2017/0432)
PRINCIPAL INVESTIGATOR: DR DEVESH RAMDHANI
SUPERVISOR: PROF RY SEEDAT
PROJECT TITLE: QUALITY OF LIFE ASSESSMENT IN PATIENTS WITH ALLERGIC RHINITIS

APPROVED

1. You are hereby kindly informed that, at the meeting held on 29 August 2017, the Health Sciences Research Ethics Committee (HSREC) approved this protocol after all conditions were met.
2. The Committee must be informed of any serious adverse event and/or termination of the study.
3. Any amendment, extension or other modifications to the protocol must be submitted to the HSREC for approval.
4. A progress report should be submitted within one year of approval and annually for long term studies.
5. A final report should be submitted at the completion of the study.
6. Kindly use the **HSREC NR** as reference in correspondence to the HSREC Secretariat.
7. The HSREC functions in compliance with, but not limited to, the following documents and guidelines: The SA National Health Act. No. 61 of 2003; Ethics in Health Research: Principles, Structures and Processes (2015); SA GCP(2006); Declaration of Helsinki; The Belmont Report; The US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US Department of Health and Human Services- (HHS), 21 CFR 50, 21 CFR 56; CIOMS; ICH-GCP-E6 Sections 1-4; The International Conference on Harmonization and Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Tripartite), Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines, Constitution of the HSREC of the Faculty of Health Sciences.

Yours faithfully

DR SM LE GRANGE
CHAIR: HEALTH SCIENCES RESEARCH ETHICS COMMITTEE

Health Sciences Research Ethics Committee
Office of the Dean: Health Sciences
T: +27 (0)51 401 7795/7794 | E: ethicslhs@ufs.ac.za
Block D, Dean's Division, Room D104 | P.O. Box/Posbus 339 (Internal Post Box G40) | Bloemfontein 9300 | South Africa
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Appendix F – Free State Department of Health Approval

health
Department of Health
FREE STATE PROVINCE

19 June 2017

Dr D Ramdhani
Dept. of Otorhinolaryngology
Faculty of Health Science
UFS

Dear Dr D Ramdhani

Subject: Quality of life assessment in patients with allergic rhinitis.

- Please ensure that you read the whole document, Permission is hereby granted for the above – mentioned research on the following conditions:
- Participation in the study must be voluntary.
- A written consent by each participant must be obtained.
- Serious Adverse events to be reported to the Free State department of health and/ or termination of the study
- Ascertain that your data collection exercise neither interferes with the day to day running of Universitas Hospital nor the performance of duties by the respondents or health care workers.
- Confidentiality of information will be ensured and please do not obtain information regarding the identity of the participants.
- **Research results and a complete report should be made available to the Free State Department of Health on completion of the study (a hard copy plus a soft copy).**
- Progress report must be presented not later than one year after approval of the project to the Ethics Committee of the University of Free State and to Free State Department of Health.
- Any amendments, extension or other modifications to the protocol or investigators must be submitted to the Ethics Committee of the University of Free State and to Free State Department of Health.
- **Conditions stated in your Ethical Approval letter should be adhered to and a final copy of the Ethics Clearance Certificate should be submitted to** sebeelats@fshealth.gov.za **before you commence with the study**
- No financial liability will be placed on the Free State Department of Health
- Please discuss your study with the institution manager/CEOs on commencement for logistical arrangements
- Department of Health to be fully indemnified from any harm that participants and staff experiences in the study
- Researchers will be required to enter in to a formal agreement with the Free State department of health regulating and formalizing the research relationship (document will follow)
- You are encouraged to present your study findings/results at the Free State Provincial health research day
- Future research will only be granted permission if correct procedures are followed see http://nhrd.hst.org.za

Trust you find the above in order.
Kind Regards

Dr D Motau
HEAD: HEALTH
Date: 27/06/17

Head : Health
PO Box 227, Bloemfontein, 9300
4th Floor, Executive Suite, Bophelo House, cnr Maitland and, Harvey Road, Bloemfontein
Tel: (051) 408 1646 Fax: (051) 408 1556 e-mail khusemj@fshealth.gov.za/chikobvup@fshealth.gov.za

www.fs.gov.za

Appendix G – Approved Protocol

Quality of life assessment in patients with Allergic Rhinitis

Introduction:

Allergic rhinitis (AR) represents a global health problem affecting 10% to 20% of the population.[1] It is an important health problem because of its prevalence and its impact on patients' social life, school performance, and work productivity.[2] There is also an association with other medical conditions such as asthma, conjunctivitis, sinusitis and otitis media with effusion.[3]

In the USA, allergic rhinitis is responsible for 3.5 million lost working days and over $6000 million dollars spent on medical formulations, without mentioning losses in productivity, numbers of medical appointments, money spent on over-the-counter medication and other additional costs.[4]

There are few existing studies on QOL in allergic rhinitis sufferers in South Africa.[5-7]

The Rhinoconjunctivitis Quality of life Questionnaire (RQLQ) about the quality of life of the patients suffering from Rhinoconjunctivitis was first prepared by Juniper and Guyatt in 1991 and has been validated and is used worldwide in allergic rhinitis quality of life research.[8]

Aim:

To determine the impact of allergic rhinitis on the Quality of Life of allergic rhinitis patients attending the Ear Nose and Throat clinic at the Universitas Academic Hospital Complex.

Study Design:

Prospective study using questionnaires.

Methods:

Newly diagnosed patients will be recruited from the Ear Nose and Throat clinic on a voluntary basis after standard work up diagnosis them as Allergic Rhinitis patients. They will then be asked to complete the mini RQLQ questionnaire developed by E.Juniper.

The questionnaire will be completed at the time of diagnosis and again at a one month follow up visit. The results will be compared to determine improvement. Mean scores of each individual based on the answers to the QOL questionnaire will be calculated. (the higher the number, the worse is QOL). The minimal important difference (MID) for the mini RQLQ is 0.7. The MID has been defined as "the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management."

An estimated 50 patients will be recruited for the study.

The following information will also be documented:

- Age
- Gender
- Main presenting symptom/s
- Current medication use
- Compliance to medication use
- Comorbid diseases; asthma, eczema, food allergies
- Residential area
- Aggravating or improving factors and seasons
- Pets, underfloor heating and humidifier use
- Skin prick test results if done

Statistical Analysis:

Statistical analysis will be performed by the Department of Biostatistics.

Budget:

It is estimated that stationary and printing costs will be approximately R500. These costs will be borne by the Department of Otorhinolaryngology.

Ethical Aspects:

The protocol will be submitted to the ethics committee of the Faculty of Health Sciences of the University of the Free State for approval. Permission to perform the study will be obtained from the clinical head of Universitas Hospital.

Time Schedule:

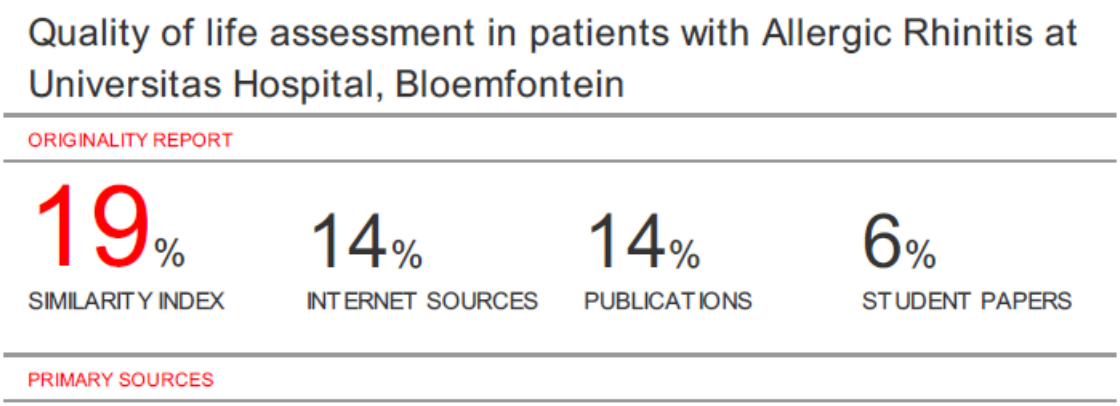
Submission to the Ethics Committee for October/November 2014 meeting.

Data collection from January 2015 to December 2015.

Statistical analysis January 2016

Report February 2016

Appendix H – Turnitin report



Quality of life assessment in patients with Allergic Rhinitis at Universitas Hospital, Bloemfontein

ORIGINALITY REPORT

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