THE PREVALENCE AND DETERMINANTS OF DRY EYE DISEASE AMONGST PEOPLE LIVING IN KWA-MHLANGA

by

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DEDICATION

This research study is dedicated to my parents. My late father Mahwele William Nkgapele and Mmaphuti Agnes Nkgapele who dedicated their lives to provide me with education. To my loving husband Sifiso Mefane who has been a source of my inspiration during my studies and putting me in his prayers. My beloved kids Nomfundo, Ted and Kutloano who always wished me all the best with my studies.

….I love you family…….

DECLARATION

I Tlou Kate Mefane declare that THE PREVALENCE AND DETERMINANTS OF DRY EYE DISEASE AMONGST PEOPLE LIVING IN KWA-MHLANGAis my own work and that all the sources that I have used or quoted have been indicated and acknowledged by means of complete references and that this work has not been submitted before for any other degree at any other institution.

Tlou Kate Mefane 24 May 2021

…… ……

Full names Date

ACKNOWLEDGEMENTS

Two years ago when I was accepted to study at University of Limpopo for MPH the desire to finish on time was too great to conceive. Thanks to the Almighty for it is such a privilege and honour to have made it thus far.

I wouldn't have made thus far without the following people who became my support system to complete my studies and for their respective contributions to this dissertation:

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Abstract

Background

Dry eye disease (DED) is defined as a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, and tear film instability with potential damage to the ocular surface. It is accompanied by increased osmolality of the tear film and inflammation of the ocular surface. DED is one of the most frequently established diagnoses in ophthalmology and represents a growing public health concern, with consequences that remain widely underestimated. There is variability of clinical manifestations and diagnostic criteria which leads to poor correlation between clinical signs and symptoms, therefore resulting in difficulties to assess prevalence of DED despite an improved understanding of pathogenic factors of acquired DED. However, its prevalence has been reported to range from 74% to 33% worldwide and the current study aimed to investigate the prevalence of DED and its determinants amongst people consulting at Focus Optometrists in Kwa-Mhlanga Township in Mpumalanga Province.

Methodology:

The current study was quantitative in nature and it followed a cross-sectional descriptive design to address the research question. The study population were people consulting at Focus Optometrists in Kwa-Mhlanga Township in Mpumalanga Province in which two standardized optometry diagnostic tests (Schimer test and the tear film break up time) were used for data collection coupled with a comprehensive case history which was taken for all participants. Data analysis was done using the STATA statistical software version 12 for Windows (STATA Corporation, College Station, Texas). Frequency tables were used to make comparisons between groups for continuous and categorical variables using student *t*-test, and chi-square test. P-value less than 0.05 at 95% confidence level were regarded as significant.

Results:

A total of 236 participants were recruited and the mean age of the participants was 39.7 in which majority of participants were females and there was a statistical significance difference in age groups of both males and females at *p-value=0.011*. Majority of the participants have reported to have experience of sensitivity to light

and foreign body sensation sometimes. The poor vision and blurred vision have been reported by majority of participants sometimes and the prevalence of dry eye disease was found to be 80.9% and the risk of the dry eye disease in the current study was found significantly increasing with old age. Those who were older (35 years above) were 4.2 times more likely to develop dry eye disease at *p-value <0.001* as compared to young participants. Female gender was found not to be protective of developing dry eye disease in the current and participants who were single, having secondary and education qualifications were more likely to develop dry eye disease. Participants with ocular conditions, systemic disease, surgery and those with high blood pressure were more likely to develop dry disease

Conclusion:

The prevalence of dry eye disease in the current study was found to be very high and therefore, patients coming to the clinic from the age of 40 with underlying systemic diseases should be screened for dry eyes. Dry eye disease can be a major contributor of refractive error in the visual systems and or can also be a sign or a symptom of hormonal or related ocular or systemic disease. More eye care awareness should be done at primary eye care level to detect the cause or to eliminate future associated symptoms.

Key concepts

Dry eye disease, blurred vision, poor vision, Schirmer test, TFBUT

Table of Contents **Page No**

Acronyms

ATD	Aqueous tear deficiency
DED	Dry eye disease
DEQ	Dry Eye Questionnaire
ICC	Intraclass correlation coefficient
KCS	Keratoconjunctivitissicca
OTC	Over the counter medication
OTC	Over the counter
SPK	Superficial punctate keratitis
TFBUT	Tear film break-up time
VADD	Vitamin A deficiency disease
WHO	World Health Organization

Definition of concepts

Dry eye disease is defined as a “multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, and tear film instability with potential damage to the ocular surface (Ervin, Law, & Pucker, 2017). In the context of this study, dye eye disease will be defined as above.

Determinants: is defined as a factor which determines the nature or outcome of something (Kenneth & Rothman, 2012). In this study, determinants will be defined as factors that will be identified to be contributing to the occurrence of dry eye diseases.

Prevalence: is a statistical concept referring to the number of cases of a disease that are present in a population at a given time (Medicinenet, 2019). In the current study, the prevalence of dry eye will be defined as the number of those patients who will be tested positive for dry eye over all the patients who would have tested during the study period.

1. CHAPTER 1

1.1. Introduction

The human eye is a part of the sensory nervous system and is the organ responsible for conscious light perception and vision (Meek & Knupp, 2015; Cioffi, 2020). Its intricate and complex anatomy has evolved to effectively focus incoming light from the surrounding environment and to harness its energy by efficiently utilizing the physicochemical properties of retinoids (Cioffi, 2020). The human eye is a relatively simple optical instrument that imposes the first performance limits on the visual system (Artal, 2015). Human eyesight is one of the most valuable assets and maintaining the health of the eyes is so important. There are many common issues which people experience with their eyes such as dry eyes, Cataracts, Keratoconus, Diabetic Retinopathy, Macular Degeneration, Refractive Errors, Glaucoma, Presbyopia, Floaters, Tearing and many more. In this current study the focus was on dry eyes, its prevalence and the determinants.

Dry eye disease is defined as a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, eye dryness, irritation, foreign body sensation, light sensitivity, itching, and tear film instability with potential damage to the ocular surface all of which eventually reduce a person's quality of life (Wei & Asbell, 2014; Messmer, 2015). It is one of the most commonly encountered problems in ocular pathology. Signs can include punctuate epithelial erosions, hyperaemia, rapid tear break-up time, and meibomian gland disease (Zeev, Miller & Latkany, 2014). Dry eye is usually classified into two major categories: aqueous-deficient dry eye, in which tear production is reduced, and evaporative dry eye, in which the evaporation of the tear film is abnormally high. Both categories have increased concentration of tear film constituents, as manifested by elevated osmolarity and rapid tearfilm breakup time (TFBUT) (Foulks, Forstot, Donshik, Forstot, Goldstein, Lemp, Nelson, Nichols, Pflugfelder, Tanzer, & Asbell, 2015).

Dry eye is a common, chronic condition that affects millions of people around the world. Dry eye sufferers frequently experience burning, foreign body sensation (something in the eye or sandy sensation), and blurry vision, which lead them to

seek medical care (Ervin et al., 2017). Dry eye disease (DED) is a common ocular condition which significantly reduces quality of life, and affects 6–34% of the global adult population. Pathological dry eye was first described as keratoconjunctivitissicca (KCS) over 70 years ago, and although DED and KCS are not strictly synonymous (as DED can present without keratitis) (Foulks, Forstot, Donshik, Forstot, Goldstein & Lemp et al., 2015). Although often disregarded as a minor problem, keratoconjunctivitissicca, commonly referred to as dry eye, is a growing public health concern affecting as many as 17% of women and 11.1% of men in the United States (Hessen, & Akpek, 2014). This is likely an underestimate if one also considers self-treating patients and milder/periodic cases with intermittent symptoms (Hessen & Akpek, 2014).

The prevalence of dry eye syndrome increases with age and affects a significant percentage of the population, especially those older than 50 years of age. Middle-aged and older adults are the most commonly affected group because of the high prevalence of contact lens usage, systemic drug effects, autoimmune diseases, and refractive surgeries in these groups (Phadatare, Momin, Nighojkar, Askarkar & Singh, 2015). Prevalence estimates of dry eye disease and severe symptoms have largely varied by study, ranging between 5% and 35% (Paulsen, Cruickshanks, Fischer, Huang, Klein, Klein, & Dalton, 2014). The existing but insufficient epidemiological information on DED in developing countries, particularly in Africa, have invariably been reported as a small part of the 'bigger picture' of DED which is often associated with infectious and non-infectious conditions like trachoma and vitamin A deficiency disease (VADD) (Osae, Gehlsen, Horstmann, Siebelmann, Stern & Kumah & Steven, 2017). The overall prevalence of dry eye in South Africa seems to be increasing, as a number of South African practitioners report seeing more (DED) patients (Castelyn, Majola, Motilal, Naidu, Ndebele & Vally et al., 2015).

In this study the prevalence and the determinants estimates of dry eye disease and severe symptoms have largely varied. Limited research on this topic has been one in the South African context, particularly in rural areas. The current study is important because it will inform the development of public health policies and primary health care practitioners in both private and public space. Since the

study was to test tear quality and quantity the study indicates that people with deficiency of tears has poor tear quality. The questionnaire was also a supporting tool to confirm the results. This chapter will present the background to the study; a statement of the problem; a literature review; the purpose of the study, along with the research aims and objectives; the research methodology employed; ethical considerations and the significance of the research.

1.2. Problem statement

Dry eye disease (DED) is well recognised global public health problem affecting millions of people because of its high prevalence and morbidity (Tan, Morgan, Cai, & Straughan, 2015). Although common in the general adult population, the exact prevalence of dry eye disease is not known and has been estimated between 6% and 34% (Malet, Le Goff, Colin, Schweitzer, Delyfer & Korobelnik et al., 2014). As dry eye is considered a symptomatic condition, accurate evaluation of symptoms is of paramount importance for its diagnosis in the context of epidemiological studies. The dry eye epidemiologic studies looking into the prevalence and risk factors of the disease are rare in South Africa, thus there is paucity of scientific information on the epidemiology of dry eye and its determinants in rural populations such as Kwa-Mhlanga Township in Thembisile Hani municipality of Mpumalanga Province in South Africa. Therefore, it was significant in this study to investigate and describe the prevalence of DED in rural areas of Kwa-Mhlanga Township to identify causes and risk factors that linked with DED. An understanding of epidemiological differences in these areas will also facilitate understanding of specific pathologies and the choice of therapeutic modality.

1.3 PURPOSE OF THE STUDY

1.3.1 Aim of the study

The aim of the current study was to investigate the prevalence and the determinants of dry eye disease amongst people consulting at Focus Optometrists in Kwa-Mhlanga Township in Mpumalanga Province.

1.3.2 Objectives of the study

- To determine the prevalence of dry eye disease amongst people consulting at the Focus Optometrists in Kwa-Mhlanga Township in Mpumalanga Province.
- To investigate the determinants contributing to the cause of dry eye disease amongst people consulting at Focus Optometrists.
- To determine the association between socio-demographics factors and the determinants of dry eye disease amongst people consulting at Focus Optometrists.

1.4 RESEARCH QUESTION

What is the prevalence and determinants of dry eye disease amongst people consulting at Focus Optometrists in Kwa-Mhlanga Township in Mpumalanga Province?

1.5 RESEARCH METHODOLOGY

1.5.1 Research design

Research design is defined as type of inquiry within qualitative, quantitative and mixed methods approaches used to provide specific direction for designing research (Creswell, 2013). A cross-sectional descriptive study design was used to help address the research question posed in this study including other variables of interest as they exist within a defined population at a particular point in time (Detels, Gulliford, Karim & Tan, 2015).

1.6.2 Sampling Data collection and analysis

Convenience sampling was used in the current study. which is a non-probability sampling technique in which data collection is done from population of members who are conveniently available to participate in a study. The members of a target population met certain practical criteria, such as easy accessibility, geographical proximity, availability at a given time or the willingness to participate (Etikan, Musa & Alkassim, 2016). In this study, participants who were consulting at Focus Optometrists in Kwa-Mhlanga Township in Mpumalanga Province were recruited to participate. The current study used two data collection tools which are the diagnostic tests which allowed patients to be classified into one of two treatment-based subgroups,

"aqueous-deficient" or "hyperevaporative." and the questionnaire for comprehensive history taking, which was translated from English to Ndebele by personnel from the Linguistics department at the University of Limpopo. Secondly, clinical tests Schirmer test and TFBUT such as were used to diagnose dry eye due to their high reliability. Data analysis was done using the STATA statistical software version 12 for Windows (STATA Corporation, College Station, Texas). A detailed description of the methodology followed including how reliability and validity of the data was achieved including the data analysis and the measures to minimise bias is presented in chapter 3.

1.7 ETHICAL CONSIDERATIONS

To ensure ethical considerations were taken into account in this study; permission to conduct the study was sought from University of Limpopo's Turfloop Research Ethics Committee and then from the Mpumalanga Department of Health Provincial. In addition, a storage system was implemented to store the collected data and records were kept in such a manner as not to reveal the identity of the patients in order to ensure their confidentiality, privacy and anonymity. There were no foreseeable risks associated with participation in this study.

1.8 SIGNIFICANCE OF PROPOSED RESEARCH

DED is well recognised as a global public health problem affecting millions of people because of its high prevalence and morbidity. As dry eye is considered a symptomatic condition, accurate and scientific investigation of the prevalence and determinants of dry eye will assist in the understanding of the epidemiological dynamics of dry eye in rural populations such as those in Kwa-Mhlanga Township` Thembisile Hani municipality, in Mpumalanga South Africa.

1.9 CONCLUSION

The information presented above provided an overview of this study. The next chapter, which is Chapter 2, describes the literature review which was done to highlight previous research studies conducted across the globe on this research topic. Chapter 3 will highlight the research methodology employed; Chapter 4 dealt with the presentation and representation of the study's research findings,

while Chapter 5 presents a summary of the study and recommendations emanating from the results of this study.

2. CHAPTER 2: LITERATURE REVIEW

2.1. Introduction

A literature review is a summary of previous research on the topic of interest, checking on how it was conducted and how the problem was solved. In this study the literature review will focus dry eye disease including its diagnosis, treatment and prevention; the prevalence of dry eye globally, continentally and nationally and lastly the determinants of dry eye disease and public health intervention to reduce and prevent the occurrence of dry eye disease.

2.2. Dry eye disease

DED is a serious health problem and its pathophysiology together with the aetiology are poorly understood and most likely multiple mechanisms are involved (Vehof, Kozareva, Hysi, & Hammond, 2014). Dry eye has been shown to affect visual system functioning, including visual acuity, as well as to have a negative impact on some health-related quality-of-life measures. It has also been found to be correlated with anxiety and depression (Paulsen et al., 2014). It is a long-term condition that is known to cause eye discomfort and visual disturbances like blurred vision. This condition affects millions of people around the world, and the first-line treatment for dry eye is typically over the counter (OTC) artificial tears (Pucker, Ng, & Nichols, 2016).

2.3. Diagnosis of dry eye disease

An important objective is to review recent advances in diagnosis and in grading severity and to consider their implications for patient selection criteria for clinical trials (Bron, Tomlinson, Foulks, Pepose, Baudouin & Geerling et al., 2014). Several investigations have been developed to evaluate patients complaining of ocular dryness (Cornec, Saraux, Jousse-Joulin, Pers, Boisramé-Gastrin & Renaudineau et al., 2015). There are few procedures that could be followed or applied to diagnose dry eye such as the Schirmer's test, Break-Up Time (Aguilar, Marquez, Albera, Tredicce, & Berra, 2014; Cornec et al., 2015).

2.4. Treatment of dry eye disease

There are relatively few effective treatments for DED, especially for severe disease. Clinical development of new DED treatments is slow, partly because of problematic diagnosis and classification. (Baudouin, Aragona, Van Setten, Rolando, Irkeç & del Castillo et al., 2014). Effective treatment modalities that can reverse, or at least stop this progression, are scarce (Wei & Asbell, 2014). One common treatment for dry eye is artificial tears, which provide lubrication to the surface of the eye. However, artificial tears lack the biological nutrients found in natural tears that are critical to maintenance of the tear film. Eye drops made by separating liquid and cellular components of the patient's blood, known as autologous serum eye drops, have been shown to possess many of the same biological nutrients found in natural tears. Because of this fact, serum eye drops, eye ointments and eye gels are believed to be a better tear substitute and have been proposed as treatment for dry eye (Pan, Angelina, Marrone, Stark, & Akpek, 2017).

The typical first-line treatment for dry eye is over-the-counter artificial tears (eye drops). If these fail to relieve symptoms, persons with dry eyes may receive other treatment. Punctual plugs are one type of advanced dry eye treatment; they work by blocking the tear ducts (puncta) of the upper and lower eyelids. Punctual plugs come in several materials, shapes, and sizes (Ervin et al., 2017). DED pathogenesis

and presentation is multifarious, and symptomatology and signs of DED can be inconsistent. Many disease severity criteria currently used by ophthalmologists are confounded by complex disease subtypes and a lack of standardisation, and the selection of single criteria for assessment of disease severity is therefore fraught with difficulties. This lack of dependable diagnostic criteria for disease progression and therapeutic response can undermine clinical trial success and complicate clinical decision making (Baudouin et al., 2014). Punctal occlusion is a mechanical treatment that blocks the tear drainage system in order to aid in the preservation of natural tears on the ocular surface (Ervin, Law, & Pucker, 2017).

2.5. The burden of dry eye disease

The prevalence of dry eye symptoms (also called xerophthalmia) varies widely across epidemiological studies (Cornec et al., 2015; Alshamrani, Almousa, Almulhim, Alafaleq, Alosaimi & Alqahtani et al., 2017), from 6% to more than 34% (Vehof et al., 2014; Cornec et al., 2015) depending on the population studied (Vehof et al., 2014; Alshamrani et al., 2017). Dry eye disease is more common in women than in men, and its frequency increases with age. Overall, approximately one in four patients attending ophthalmology clinics are reported to be having dry eye symptoms (Cornec et al., 2015).

2.5.1. Global prevalence of dry eye disease

Epidemiological studies have indicated increasing incidence of DED in the worldwide population (Alves, Novaes, Morraye, Reinach, & Rocha, 2014). The estimated number of people affected by DES ranges from 25 to 30 million all over the world (Phadatare et al., 2015). In the United States (US), estimates have ranged from 4.3% among men aged ≥50 years to 21.6% in men and women aged 48–91 years and 14.5% among those aged ≥21 years (Galor, Feuer, Lee, Florez, Carter & Pouyeh et al., 2011; Farrand, Fridman, Stillman, & Schaumberg, 2017). A study conducted in America by Uchiono et al (2011) reported that an estimated 7.8% or 3.23 million American women and 4.7% or 1.6 million men >50 years old have DED. Tens of millions or more have less severe symptoms and probably a more episodic manifestation of disease that is notable only during exposure to some contributing factors (Uchino, Nishiwaki, Michikawa, Shirakawa, Kuwahara & Yamada et al., 2011).

2.5.2. Dry eye disease in Africa

The existing but insufficient epidemiological information on DED in developing countries, particularly in Africa, have invariably been reported as a small part of the ‘bigger picture’ of DED (Osae et al., 2017). Hospital- and population-based epidemiological data, across all ages, on DED is scarce in these resource-deficient settings, especially in sub-Saharan Africa (Onwubiko, Eze, Udeh, Arinze, Onwasigwe, & Umeh, 2014). The prevalence of DED in Aluu a rural community of Nigeria was found to be at 27.4% (Onua, & Chukwuka, 2017). In a study conducted in Sohag city, south of Cairo, Egypt, reported an

overall prevalence of dry eye of 22.8% which was significantly more prevalent in patients 45 years or older (with a prevalence of 71.7%) compared with those younger than 45 years of age (Mostafa, 2016). In certain respects, the epidemiology of DED in Africa is comparable with Latin America and Asia, where DED has been shown to be associated with infectious conditions and malnutrition like leprosy and vitamin A deficiency, respectively (Osae et al., 2017).

2.5.3. Dry eye disease in South Africa

The overall prevalence of dry eye in South Africa seems to be increasing, as a number of South African practitioners report seeing more dry eye patients. In a study conducted at University of KwaZulu-Natal in South Africa using ocular surface disease index (OSDI), it was reported that 41% of the participants had some dry eye disease symptoms and clinical testing showed that 81% of the participants had dry eye. In this same study, half of the black participants 32% had dry eye symptoms and 80% had clinical signs of dry eye (Castelyn et al., 2015). A relatively high prevalence of 64% was reported in a study conducted in a population based study in Johannesburg, South Africa (Gillan, 2009).

2.6. Determinants of dry eye

Several risk factors have repeatedly been associated with DED in clinic-based case-control and population-based epidemiology cohorts (Vehof et al., 2014). Advanced age is considered as a major risk factor for dry eye disease (Malet, et al., 2014; Paulsen et al., 2014). Dry eye in the elderly can result from the accumulation of various other risk factors including female gender, hormonal disorders, associated disease including cataract (Malet, et al., 2014; Vehof et al., 2014; Cetinkaya, Mestan, Acir, Cetinkaya, Dadaci & Yener, 2015). Glaucoma and its medications have been found to be associated with DED, particularly eye drops containing preservatives (Vehof et al., 2014; Nowak, & Smigielski, 2016) and also the use of drying medications such as antidepressants, anxiolytics and antihistamines, or preservative-formulated eye drops (Malet, et al., 2014).

Dry eye disease is seen with increased prevalence in patients with autoimmune diseases, which affect approximately 8% of the population, of whom 78% are

women (Malet, et al., 2014; Vehof et al., 2014). Dry eye disease also affects postmenopausal women (Vehof et al., 2014) and the elderly (Gayton, 2009). Other medical conditions that can lead to dry eyeare connective tissue diseases, Diabetes Mellitus, systemic hypertension and ocular diseases like blepharitis, chronic conjunctivitis, meibomitis and pterygium (Cetinkaya et al., 2015; Phadatare et al., 2015). There is evolving scientific knowledge that that environmental factors (Alves, Novaes, Morraye, Reinach & Rocha, 2014) can contribute to DED. This is supported by some recent studies and reflects differences in cultural traditions and exposure to unfavorable working conditions (Alves et al., 2014; de Kluizenaar, Roda, Dijkstra, Fossati, Mandin & Mihucz et al., 2016).

3. CHAPTER 3: METHODOLOGY

3.1. Study design

Research design is an aspect of the research that assists the researcher in organizing factors that could interfere with the validity of findings (Leavy, 2017). It is a plan that guides the arrangement of the condition for collection and analysis of data (Terre Blanche, Durkheim & Painter, 2014). The current study was using cross-sectional quantitative method which involved the process of collecting, analysing, interpreting and writing the results of a study (Creswell & Creswell, 2018). Cross-sectional study is an observational research type that analyses the relationship between diseases or other health-related characteristics and other variables of interest as they exist in a defined population at a particular point in time (Hengartner, Kawohl, Haker, Rössler & Ajdacic-Gross, 2016; Zucoloto, Maroco & Campos, 2016.

3.2. Study setting

The study setting refers to the actual place and conditions or circumstances where and within which the research study takes place (Pilot & Beck, 2012). The research was conducted at Thembisile Hani Local Municipality located in the Nkangala District Municipality of Mpumalanga Province, South Africa (Figure 1).

It is a semi-urban local Municipality consisting of 57 villages within which there are 5 established townships.

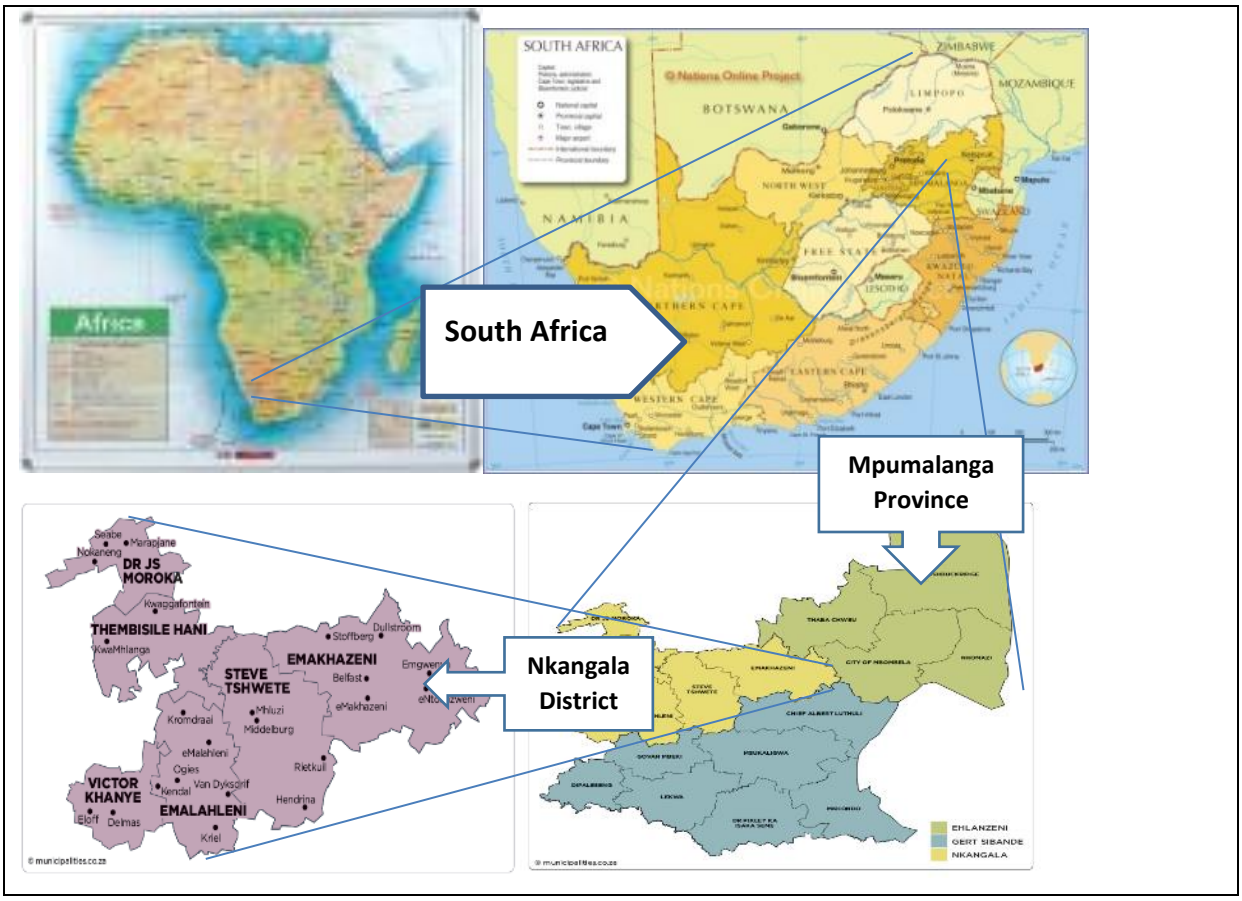


Figure 1 Maps of Africa showing South Africa, Mpumalanga Province, Thembesile Hani Municipality located inKangala District.

3.3. Study population

The study population study was the residents of a given population members that conform to a set of specifications from which researcher sample was drawn but the hypothetical target population is larger (Thygesen & Ersbøll, 2014). The study population were people consulting at Focus Optometrists in Kwa-Mhlanga Township in Mpumalanga Province.

3.3.1. Inclusion criteria

All people consulting at Focus Optometrists in Kwa-Mhlanga Township in Mpumalanga Province being in the age group 18 years and above were included to participate in the study.

3.3.2. Exclusion criteria

All people consulting at Focus Optometrists in Kwa-Mhlanga Township in Mpumalanga Province being in the age group 18 years and above who refuse to consent to be part of the study and those will be mentally unstable were excluded to participate in the study.

3.3.3. Sampling and sample size

Sampling is the process of selecting the subset or portion of the population to represent the identified population (Botma, Greeff, Mulaudzi & Wright, 2010). In this study, simple random sampling was utilized to select the sample, where all people who consult at Focus Optometrists between October and December 2020 will form part of the study. A six (6) step in excel was also used to random select the records (Mélard, 2010). The first step was the compilation of a list of appointments of people who were consulting on a weekly basis and excel spreadsheet was created. An addition of a row to the right Column of the numbers was done and named “Random Sample”. Then in B2 the formula “=RAND()” was typed and press enter to assign a random number. Thirdly, B2 cell was right clicked to repeat the function for all the rows then sort on Column B named “Random Sample” and all data was highlighted to select sort from the Data tab. Then sort by Column B. The rows were randomized and grouping of the people was selected to participate in the study. This process was conducted on a weekly basis until the sample size is reached.

Cochran’s formula (Hemmati, Dabbaghi, & Mahmoudi, 2018) for calculating sample size when the population is infinite was used to calculate the sample size in the current study as follows:

$$n_0 = \frac{z^2 pq}{e^2}$$

where, n_0 is the sample size,

z is the selected critical value of desired confidence level which is 1.96,

p is the estimated proportion of an attribute that is present in the population currently 81% of dry eye in a study conducted in South Africa eye (Castelyn et al., 2015).

therefore:
p will be 0.81
q=1- *p* and
e is the desired level of precision which is 0.05

$$n_0 = \frac{(1.96)^2\ 0.81(1-0.81)}{(0.05)^2}$$

$$n_0 = \frac{(3.84)\ 0.154}{(0.0025)}$$

$$n_0 = \frac{0.591}{0.0025}$$

$$n_0 = 236$$

The sample size was 236.4 which was converted to 236 participants.

3.4. Data management

Research data management as defined by Whyte and Teddsas, ‘‘the organisation of data, from its entry to the research cycle through to the dissemination and archiving of valuable results (Pinfield, Cox & Smith, 2014). In this study, data management covered the data collections tools, data collection processes including reliability, validity and objectivity of the collected and lastly statistical data analysis.

3.4.1. Data collection tools

The current study used two data collection tools which are the standardized optometry diagnostic tests (Epstein, Karpecki, Mastrota, & Whitley, 2016) that allow patients to be classified into one of two treatment-based subgroups, “aqueous-deficient” or “hyper-evaporative.” and the questionnaire for comprehensive history taking (Henrich, Ramulu, & Akpek, 2014), which was

translated from English to Ndebele by personnel from the Linguistics department at the University of Limpopo.

3.4.2. Data collection process

Data collection process included case history taking and there are a number of clinical tests that can be used to diagnose dry eye (Castelyn et al., 2015), but the two commonly used tear tests are the Schirmer test and tear film break up time (TFBUT)TFBUT which were used in the current study due to their high reliability. These processes have been outlined here under in details.

3.4.2.1. Case history

A comprehensive case history was taken for all participants before any procedure was done on testing the tear quality and quantity. Case history taking included questions that seek to establish if a participant has had any symptoms related to exposure to known causative factors of dry eye such as electronic display terminals, air conditioning, dusty environments, etc. Furthermore, questions on family history of systemic diseases such as hypertension and diabetes mellitus were asked. Other questions which were included those that aimed to establish if any form of surgery was done on the surface of the eye as well as there were any prescribed medications being taken (Castelyn et al., 2015).

3.4.2.2. Schirmer test.

The Schirmer test is considered one of the most useful in detecting the severest, most tear deficient dry eye. It was first described by Schirmer in 1903 and is still the method most commonly used clinically to evaluate aqueous tear production (Lu, Tao, Hu, Tao, & Lu, 2018). The Schirmer test can be performed in two ways where in firstly it can be performed without the administration of a topical anaesthetic (Schirmer 1), where both the basal and reflex secretion of the tears is measured. Alternatively, the Schirmer 2 test can be performed by instilling a local anaesthetic before

insertion of the Schirmer strip, and thus only the basal secretion rate will be tested. A wet portion of the strip less than 5 mm is considered abnormally low (Karampatakis, Karamitsos, Skriapa, & Pastiadis, 2010). Schirmer 2 was not used for participants in this study however the study used Schimer 1 in which the researcher placed a Schirmer test strip hooked onto the inferior tarsus while the participant eyes were closed. After five minutes, the strip was removed and the wet length measured with a millimetre ruler.

The researcher then assessed how far the tears have travelled on the paper. A negative (more than 10 mm of moisture on the filter paper in 5 minutes) test result was regarded as normal, while less than 10mm in 5 minutes the test results was regarded as positive for dry eyes (Alves, Reinach, Paula, e Cruz, Bachette & Faustino et al., 2014).

3.4.2.3. Tear film break up time (TFBUT)

The TFBUT is used mainly to assess the quality, stability of tears and evaporative dry eye disease (Bartlett, Keith, Sudharshan, & Snedecor, 2015). Tear stability describes the effectiveness of the cohesive forces present between the three layers of the tear film. When one or more of the layers break up, the tear film will be unstable. TFBUT is the time interval between a complete blink and the first appearance of a dry spot in the pre-corneal tear film after the installation of fluorescein viewed with a cobalt blue filter. This technique has gained worldwide popularity as it is simple and convenient to perform. Even though there is a wide range of values amongst individuals, there is a general agreement that a TFBUT shorter than 10 seconds reflects tear film instability, and a TFBUT shorter than 5 seconds is a marker indicative of dry eye.

In the current study, to measure TFBUT, fluorescein was instilled into the participant's tear film and the participant was asked not to blink while the tear film is observed under a broad beam of cobalt blue illumination (Alves et al., 2014). In testing for TFBUT, sodium fluorescein dye was added to the eye and the tear film was observed under the slit lamp (blue

filter) while the patient avoids blinking until tiny dry spots develop. Generally, >10 seconds will be regarded as normal, 5 to 10 seconds, marginal, and <5 seconds will be considered low.

3.4.3. Data analysis

Data analysis is the process of systematically applying statistical and/or logical techniques to describe and illustrate, condense and recap, and evaluate data. This process is used to develop answers to questions through the examination and interpretation of data (Sharma, 2018). The basic steps in the analytic process consist of identifying issues, determining the availability of suitable data, deciding on which methods are appropriate for answering the questions of interest, applying the methods and evaluating, summarizing and communicating the results. In the current study, all data collected was analysed using STATA statistical software version 12 for Windows (STATA Corporation, College Station, Texas). Comparison between groups for continuous and categorical variables was performed using student *t*-test, and chi-square test, respectively. P-value less than 0.05 at 95% confidence level were regarded as significant thus reflecting on both descriptive and inferential statistics.

3.4.4. Reliability, Validity and Objectivity

3.4.4.1. Reliability

Reliability refers to the consistency of a measuring test (Lu et al., 2018). In the current study, internal consistency reliability of the questionnaire were evaluated by Cronbach's alpha coefficient and the test-retest reliability of the questionnaire were tested by the intra-class correlation coefficient (ICC) (Abetz, Rajagopalan, Mertzanis, Begley, Barnes & Chalmers et al., 2011).

3.4.4.2. Validity

Validity is when the instrument is able to produce results that reflect the purpose it was initially designed to measure (Bastos, Duquia, Ganzalez-Chica, Mesa & Bonamigo, 2014).

Internal validity is the degree to which a study is free from bias or systematic errors (A Dictionary of Epidemiology, 2014; Lu, Tao, Hu, Tao, & Lu, 2018). To ensure internal validity, the questionnaire was checked by the researcher's supervisor to ensure the validity of this data collection tool. This questionnaire was also subjected to review by the research committees within the University of Limpopo to improve its validity. In addition, a pilot study was conducted to test the questionnaire questions so that questions could be rephrased, if necessary, to ensure that the questionnaire measured what it intended to measure. The pilot study was conducted at approximately 10 patients at the same practice and these patients were not included in the main study.

External validity is the extent to which the results of a study can be generalised to other populations and settings (Cozby& Bates, 2015). The sample size in this study afforded the data collection tool good external validity, as the size was representative of the patients seen at the Focus Optometrist practice.

3.5. Bias

Bias is described as any tendency which prevents fair consideration of a research question (Pannucci & Wilkins, 2010). There were different types of bias which were identified in the current study as they are described below including the measures to minimise them:

3.5.1. Selection bias

Selection bias occurs when individuals or groups in a study differ systematically from the population of interest leading to a systematic error in association or outcome (Pannucci & Wilkins, 2010). In this research the researcher adhered to inclusion and exclusion criteria to minimise selection bias.

3.5.2. Sampling bias

Sampling bias is a stochastic variable that are collected to determine its distribution are selected incorrectly and do not represent the true distribution

because of non-random reasons (Pannucci & Wilkins, 2010). The researcher minimised selection bias by using simple random sampling of participants to ensure that participants who were sampled all have equal chance of participating in the study.

3.5.3. Procedural bias

Procedural bias is where an unfair amount of pressure is applied to the subjects, forcing them to complete their responses quickly (Pannucci & Wilkins, 2010). The participants were notified that their normal consultation process will form part of the study and therefore, they won't be inconvenienced to participate in the study with regard to taking much of their time.

3.5.4. *Measurement bias*

Measurement bias refers to any systematic or non-random error that occurs in the collection of data in a study and this is also called detection bias in a broad term. In the current study, measurement bias was minimised by using standard optometric procedures which was calibrated after participants' data collection procedure.

3.5.5. Volunteer bias.

Volunteer bias is systematic error due to differences between those who choose to participate in studies and those who do not (Pannucci & Wilkins, 2010). In the current study, volunteer bias was minimised by not allowing participant to volunteer to participate in the study. This was adhered to by using simple random sampling technique.

3.5.6. *Unavoidable bias*

The unavoidable bias which might have been encountered in the study was response bias. This is a type of a bias where the participants consciously, or subconsciously, gives response that they think that the interviewer wants to hear.

3.6. ETHICAL CONSIDERATIONS

Research ethics plays an important role, striving to make possible that any research study is conducted in due ethical procedures. Clinical research basically focuses on improving human health individually by improving current trends, methodologies and identifying innovative methods of treatment (Khan, Tareen & Sultan, 2016). The current study was conducted in line with the South African Health Act **61 of 2003,** to comply with the norms and standards, or guidelines, set for the conducting of research in terms of the National Health Act (Senkubuge & Mayosi, 2012).

3.6.1. Ethical approval

The study proposal was presented at Department of Public Health Research Committee for review and further presented at the School of Health Care Sciences Research Committee (SREC) and later at the Faculty Higher Degree Committee (FHDC). Then application for ethical clearance was made to the Turfloop Research Ethics Committee (TREC) at University of Limpopo.

3.6.2. Permission to conduct the study

Permission to conduct the study was requested and obtained at Focus Optometrists.

3.6.3. Informed consent

Informed voluntary consent given by a subject or a responsible proxy (e.g., a parent) for participation in a study after being informed of the purpose, methods, procedures, potential benefits and potential harms, and, when relevant, the degree of uncertainty about such outcomes (A dictionary of epidemiology, 2014). Participants who were 18 years and above were handed an information letter for the study as well as the consent form to sign before participating in the study (**See Appendices E and F).** The researcher explained to the participants that their participation is voluntary and they can withdraw from the study at any time if they wish to do so and there will be no penalties (autonomy). The consent form was also given to the Focus Optometrist manager to allow for the study to be conducted at the practice.

3.6.4. Measures to protect participants' confidentiality, privacy and anonymity

Medical research must protect the life, health, dignity, integrity, privacy and confidentiality of research participants' personal information (Helsinki Declaration Fortaleza Brazil, 2013). Information provided by the participants was kept confidential, stored and only the researcher and research supervisor/co-supervisor have access to the storage system i.e. hard drive, compact disc and file for hard copies. Participants' identity was not revealed during research report writing or presentation and if participants give permission, pseudonyms were be used. To maintain anonymity of participants, participants were never requested to write down their names as well as identity number on the questionnaire. Questionnaires were numbered participant 1, participant 2…

3.6.5. Minimisation of risks

There were no foreseeable risks to the participants as no samples i.e. blood will be drawn from participants. Participants who show signs of emotional distress were referred accordingly to the counsellors at the nearest health facility.

3.6.6. Participants and institutions/health facilities benefit from the study

The findings of the research will be presented to the Mpumalanga Department of Health and Focus Optometrist. These findings could yield advice that can be used by the health professionals who provide health services to optometry patients regarding the burden of dry eye and its determinants.

3.6.7. Compensation for Research-related Costs and Inconvenience

Participants were not compensated for participating in the study.

3.6.8. Harm

The World Health Organization (WHO) has characterized patient's safety as key with an aim to reduce adverse events to patient's health and minimize the risk of unnecessary harm associated with health care (de França, de Lima Fernandes, Pinto, de Mesquita & Xavier et al., 2016). Unnecessary harm as a focus, especially in the case of dry eye, the optometrist acted through strategies to promote ocular integrity and specific prevention. From this

perspective, the researcher identified the individuals' health/illness situations and design an individualized and comprehensive nursing care, grounded in scientific knowledge. The current study did not identify any potential harm and therefore, the identified social workers were not called to assist in managing nor preventing harm, including harms related to interfering with a participant's autonomy.

4. CHAPTER 4: RESULTS

4.1 Introduction

This chapter describes the analysis of the data and the interpretation of the research findings, which were guided by the research question posed in the study. The data was analyzed to investigate the prevalence and the determinants of dry eye disease amongst people consulting at Focus Optometrists in Kwa-Mhlanga Township in Mpumalanga Province.

4.2 Data management and analysis

After the data collection process was finalized, the completed database was securely stored. The information was captured on a Microsoft Excel spreadsheet then stored on a compact disc for confidentiality and privacy reasons. Descriptive statistical analysis was undertaken using the STATA statistical software version 12 for Windows (STATA Corporation, College Station, Texas) in order to identify frequencies and percentages of answers to the research questions. The statistical significance of the relationships between the selected variables was determined using the t-test. The level of significance was set at 0.05. All recruited participants did agree to take part in the current study and the response rate was 100%.

4.3 Research results

4.3.1 Demographics of the participants

Table 4.1 below presents the demographics of the study participants and the mean age of the participants was found to be 39.7 ± 13.7 years (Females: 38.01 ± 12.9 years and Males 42.2 ± 14.5). Majority of participants were females and there was a statistical significance difference in age groups of both males and females at *p-value=0.011*. majority of the participants were married at 55.9% for males and 57.3% for females followed by those who were single at 40.9% for males and 39.2% for females. The difference in marital status, employment status and systemic disease between males and females did not show any statistical significance.

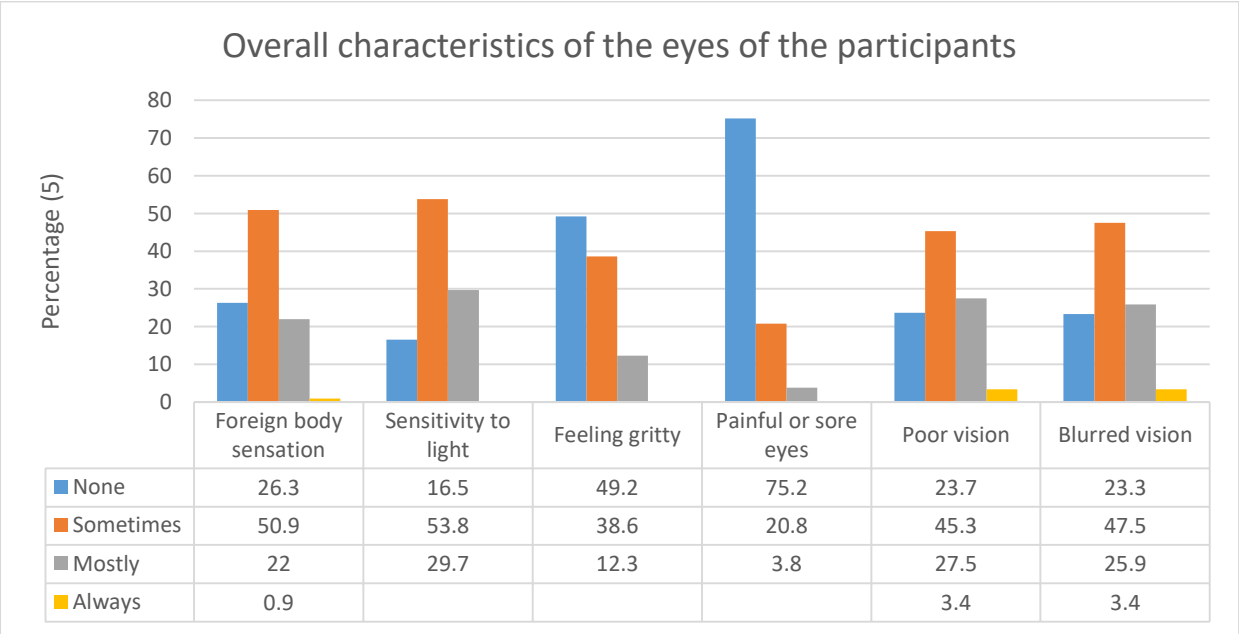
Table 4.1 Socio-demographic characteristics of participants

Socio-demographic profile		**Males (n=93)**	**Females (n=143)**	***p*-values**
		n (%)	**n (%)**	***p*-value**
Age group in years				
	18-24	15 (16.1)	21 (14.7)	0.011
	25-34	11 (11.8)	35 (24.5)	
	35-44	22 (23.7)	47 (32.9)	
	45-54	29 (31.2)	24 (16.8)	
	≥ 55	16 (17.2)	16 (11.2)	
Marital status				
	Single	38 (40.9)	56 (39.2)	0.619
	Married	52 (55.9)	82 (57.3)	
	Divorced	1 (1.1)	4 (2.8)	
	Widowed	2 (2.2)	1 (0.7)	
Employment status				
	Professional	35 (37.6)	65 (45.5)	0.596
	Semi-professional	15 (16.1)	16 (11.2)	
	Student	15 (16.1)	20 (14.0)	
	Unemployed	21 (22.6)	35 (24.5)	
	Pensioner	7 (7.5)	7 (4.9)	
Systematic disease				
	No	57 (61.3)	105 (73.4)	0.050
	Yes	36 (38.7)	38 (26.6)	
Type of systematic diseases				
	None	59 (63.4)	104 (72.7)	0.419
	High BP	29 (31.2)	34 (23.8)	
	Diabetes	4 (4.3)	3 (2.1)	
	High BP and Diabetes	1 (1.1)	2 (1.4)	

4.3.2 Prevalence of dry eye

4.3.2.1 Self-reported prevalence of dry eye

The overall characteristics of the eyes of the participants are presented in Figure 4.1 below. Majority of the participants have reported to have foreign body sensation sometimes at 50.9% while 53.8% reported to have experience of sensitivity to light. Approximately 49.2% of the participants reported not to have feeling gritty in their eyes while 75.2% reported not to have painful or sore eyes. The poor vision and blurred vision have been reported by majority of participants sometimes at 45.3% and 47.5% respectively.



	Foreign body sensation	Sensitivity to light	Feeling gritty	Painful or sore eyes	Poor vision	Blurred vision
None	26.3	16.5	49.2	75.2	23.7	23.3
Sometimes	50.9	53.8	38.6	20.8	45.3	47.5
Mostly	22	29.7	12.3	3.8	27.5	25.9
Always	0.9				3.4	3.4

Figure 4.1 Overall characteristics of the self-reported.

Table 4.2 below presents the characteristics of the eyes of the participants stratified by gender. More males reported to have foreign body sensation sometimes in their eyes at 51.6% while females were at 50.4%. Only 1.4% of females have reported to always have foreign body sensation sometimes in their eyes. Majority of females reported to experience sensitivity to light at 59.4%. The uncomfortable feeling of having sand in the eye is never fun and approximately 38% of both males and females have reported to sometimes having that gritty or irritated sensation over time. The current study findings have revealed that poor vision is common amongst males and females at 44.1% and 46.2% respectively. While blurred vision was found to be common amongst males and females at 49.5% and 46.2% respectively. Majority of the participants did not nay any ocular condition while approximately 23.7% of males have reported to have done surgery as compared to 27.3% of females.

Table 4.2 Characteristics of the eyes of the participants

		Males n (%)	Females n (%)	*p-value*
Foreign body sensation				
	None	23 (24.7)	39 (27.3)	0.650
	Sometimes	48 (51.6)	72 (50.4)	
	Mostly	22 (23.7)	30 (21.0)	
	Always	0 (0.0)	2 (1.4)	
Sensitivity to light				
	None	20 (21.5)	19 (13.3)	0.077
	Sometimes	42 (45.2)	85 (59.4)	
	Mostly	31 (33.3)	39 (27.3)	
Feeling gritty				
	None	50 (53.8)	66 (46.2)	0.174
	Sometimes	36 (38.7)	55 (38.5)	
	Mostly	7 (7.5)	22 (15.4)	
Painful or sores in the eyes				
	None	73 (78.5)	105 (73.4)	0.675
	Sometimes	17 (18.3)	32 (22.4)	
	Mostly	3 (3.2)	6 (4.2)	
Poor vision				
	None	20 (21.5)	36 (25.2)	0.511
	Sometimes	41 (44.1)	66 (46.2)	
	Mostly	30 (32.3)	35 (24.5)	
	Always	2 (2.2)	6 (4.2)	
Blurred vision				

	None	19 (20.4)	36 (25.2)	0.652
	Sometimes	46 (49.5)	66 (46.2)	
	Mostly	26 (28.0)	35 (24.5)	
Ocular condition				
	None	66 (71.0)	100 (69.9)	0.575
	Cataract	1 (1.1)	1 (0.7)	
	Glaucoma	0 (0.0)	1 (0.7)	
	Surgery	22 (23.7)	39 (27.3)	
	Cataract and wearing spectacles or had surgery	4 (4.3)	2 (1.4)	

Figure 4.2 below presents the prevalence of dry eyes amongst the participants and it was found that the prevalence of dry eyes in the current study was 80.9%.

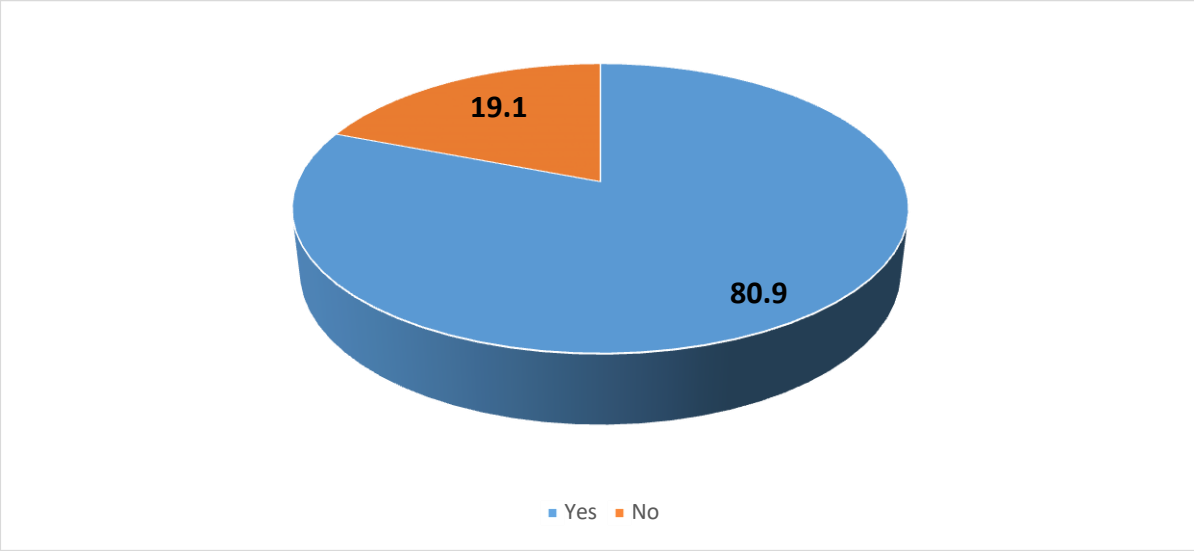


Figure 4.2 Overall prevalence of dry eye amongst the participants

Figure 4.3 below presents the overall prevalence of dry eye disease amongst the participants by age groups. It shows that the prevalence has increased with increasing age from 47.6% in age group 19 years and below to 95.8% in age group 60 years and above.

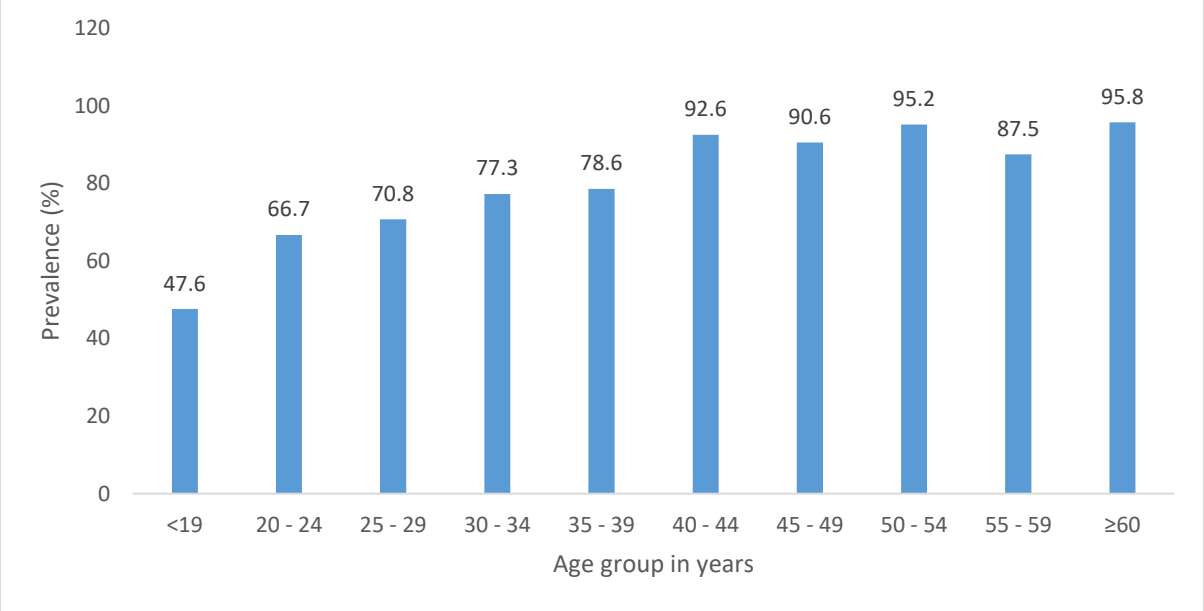
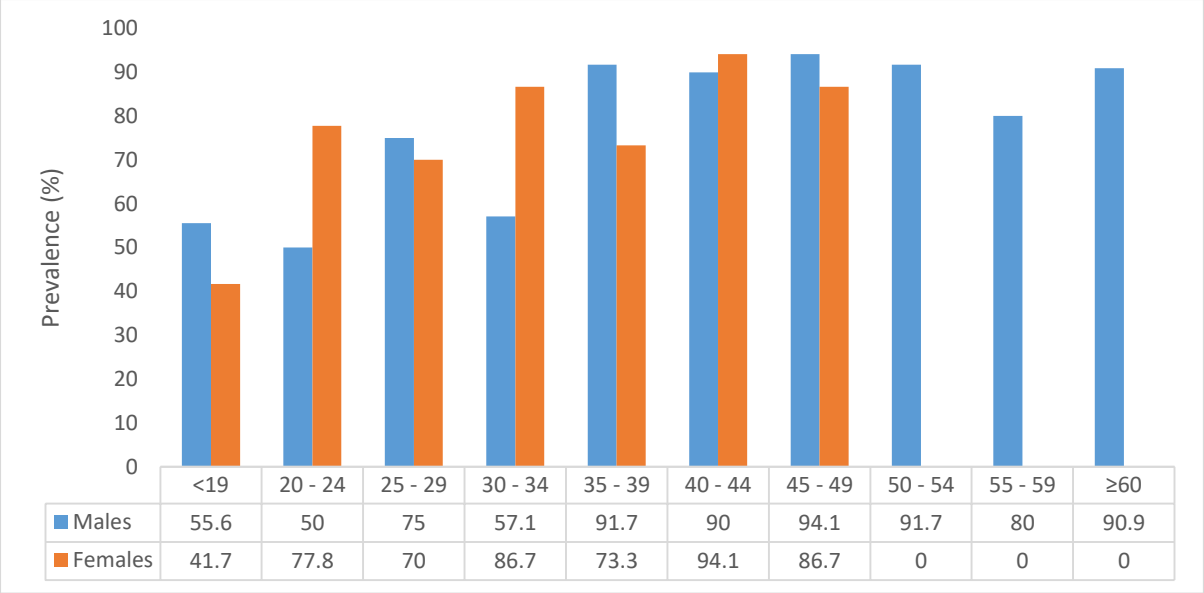


Figure 4.3 Overall prevalence of self-reported dry eye amongst the participants by age groups

Figure 4.4 below presents the prevalence of dry eyes amongst the participants by age groups stratified by gender. It has also shown that the overall prevalence of dry eye disease in the current study by gender has shown to be increasing with age. Males had a higher dry eye prevalence 55.6% in age group 19 years and below then increased to 75% at age group 24 – 29 years and to 91.7% at age group 35 – 39 years. The prevalence of dry eye then increased by 2.4% to 94.1% in age group 45 – 49 years then dropped to 80% in age group 55 – 59 years. In females, the prevalence of dry eye disease increased from 41.7% in age group 19 years followed by 77.8%, 86.7%, 94.1% and dropped to 86.7% in age groups 30 – 34 years, 40 – 44 years and 45 – 49 years respectively.



	<19	20 - 24	25 - 29	30 - 34	35 - 39	40 - 44	45 - 49	50 - 54	55 - 59	≥60
Males	55.6	50	75	57.1	91.7	90	94.1	91.7	80	90.9
Females	41.7	77.8	70	86.7	73.3	94.1	86.7	0	0	0

Figure 4.4 Overall prevalence of self-reported dry eye amongst the participants by age groups stratified by gender

Table 4.3: Overall prevalence of self-reported dry eye disease stratified by age group, gender, marital status, level of education

	Age in years				
	18-24 % (95% CI)	25-34 % (95% CI)	35-44 % (95%CI)	45-54 % (95% CI)	≥ 55 % (95% CI)
Gender					
Males	53.3 (29.0 – 76.2)	63.6 (33.5 – 85.9)	90.9 (69.6 – 97.8)	93.1 (75.9 – 98.3)	87.5 (60.9 – 96.9)
Females	57.1 (35.8 – 76.1)	77.1 (60.4 – 88.2)	80.9 (67.0 – 89.8)	91.7 (71.9 – 97.9)	–
Marital status					
Single	55.6 (39.1 – 70.9)	68.8 (50.8 – 82.4)	84.2 (60.5 – 94.9)	83.3 (36.2 – 97.8)	-
Married	–	85.7 (57.0 – 96.5)	85.4 (72.3 – 92.9)	93.3 (81.1 – 97.9)	92.6 (74.5 – 98.2)
Widowed	–	-	35.4 (1.9 – 98.1)	-	-
Divorced	57.1 (17.3 – 96.9)	25.0 (13.9 – 36.1)	12.3 (5.1 – 19.6)	10.2 (2.4 – 17.9)	3.0 (-2.9 – 8.9)
Level of education					
None or Primary	–	–	–	–	93.3 (61.4 – 99.2)
Secondary	48.3 (30.7 – 66.2)	62.5 (27.9 – 87.7)	86.7 (58.8 – 96.7)	83.3 (51.6 – 95.9)	–
Tertiary	85.7 (41.5 – 98.1)	76.3 (60.3 – 87.3)	84.9 (72.5 – 92.3)	94.7 (81.1 – 98.7)	92.9 (62.6 – 99.0)
Work status					
Working	66.7 (15.1 – 95.8)	75.8 (58.3 – 87.5)	91.5 (79.3 – 96.8)	92.1 (78.0 – 97.5)	90.0 (52.8 – 98.6)
Not working	54.5 (37.5 – 70.6)	69.2 (40.6 – 88.1)	68.2 (46.4 – 84.2)	93.3 (64.3 – 99.1)	95.5 (73.4 – 99.4)
Systemic disease					
No	55.6 (39.2 – 70.8)	74.4 (59.3 – 85.3)	81.8 (69.3 – 90.0)	81.8 (60.2 – 93.1)	83.3 (36.5 – 97.8)
Yes		66.7 (14.8 – 95.8)	92.9 (62.2 – 99.0)	-	96.2 (76.6 – 99.5)

and by systemic disease

Table 4.3 above presents the prevalence of dry eye disease stratified by age group, gender, marital status, level of education and by systemic disease. It has been found that the prevalence of dry eye has been increasing with increasing age groups also between males and females. More females at age groups 18 – 24 years and 25 – 34 years were found to be having dry eyes at 57.1% and 77.1% as compared to males at 53.3% and 63.6% respectively at similar age groups. However, it was males at age groups 35 – 44 years, 45 – 54 years and 55 years and above who had high prevalence of dry eyes a 90.9%, 93.1% and 87.5% respectively. A similar trend has been noted in the level of education as participants with tertiary educational level had a high prevalence of dry eyes at age groups 18 – 24 years and 25 – 34 years at 85.7% and 76.3% respectively as compared to 48.3% and 62.5% at similar age groups amongst those with secondary educational level. The highest dry eye prevalence was recorded amongst participants with tertiary educational level in age group 45 – 54 years at 94.7% followed by 86.7% amongst participants with secondary educational level in age group 35 – 44 years.

The highest dry eyes prevalence was recorded amongst participants who were married in age group 45 – 54 years at 93.3% followed by those in age groups 55 years and above, 25 – 34 years and 35 – 44 years at 92.6%, 85.7% and 85.4% respectively. The lowest dry eye prevalence was recorded amongst participants who were divorced in age group 55 years and above at 3%. The prevalence of dry eye amongst participants who were working increased with increasing age starting at 66.7% in age group 18 – 24 years to 92.1% in age group 45 – 55 years then dropped to 90% at age group 55 years and above. An increasing trend has been recorded amongst participants who were not working in age group 35 – 44 years at 68.2% to 95.5% in age group 55 years and above. The participants with systemic diseases had highest dry eye prevalence at 92.9% and 92.2% in age groups 35 – 44 years and 55 years and above respectively as illustrated in Table 4.3 above.

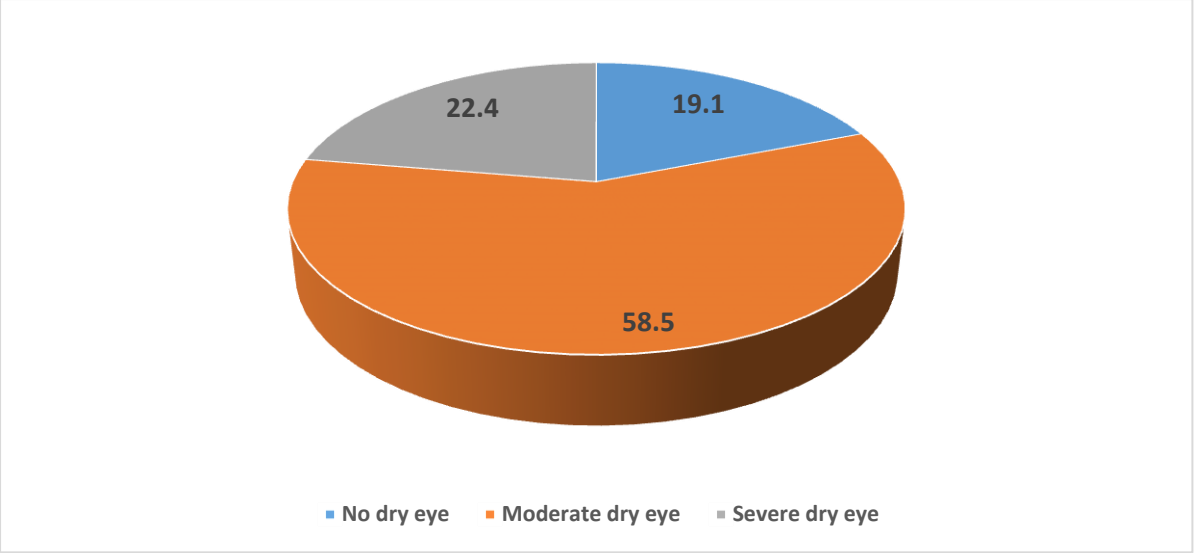
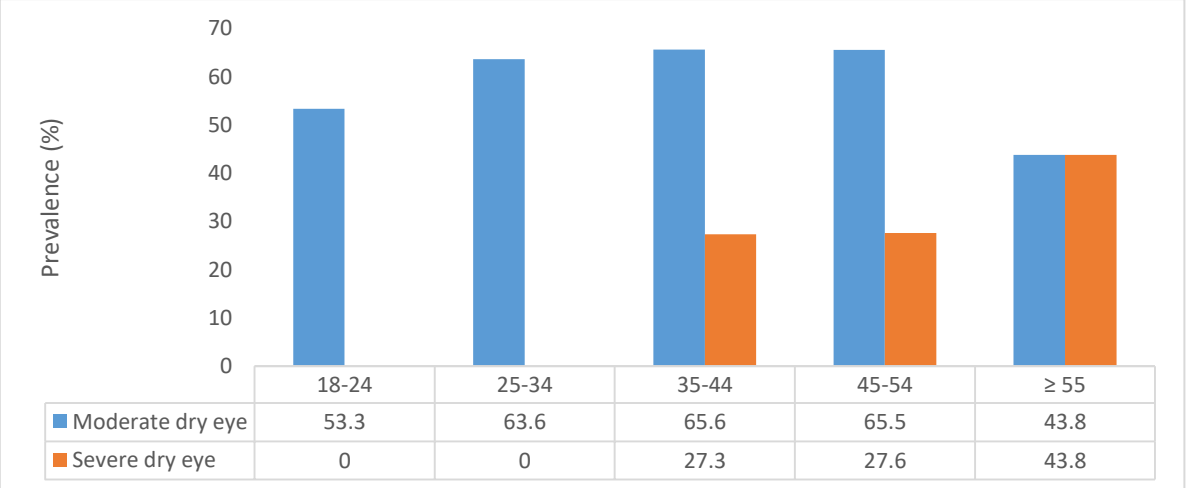


Figure 4.4 Prevalence of moderate and severe self-reported dry eye amongst the participants

The prevalence of moderate dry eyes was found to be 58.5% as compared to 22.4% of severe dry eyes as illustrated in Figure 4.4 above. Figure 4.5 below presents the prevalence of moderate and severe dry eye amongst the participants stratified by age group. The prevalence of moderate dry eyes increased with increasing age from 53.3% in age group 18 – 24 years to 65.5% in age group 45 – 54 years then dropped to 43.8% in age group 55 years and above. The prevalence of severe dry eyes was high amongst participants in age group 55 years and above at 43.8% followed by 27.6% and 26.3% in age groups 45 -54 years and 34 – 44 years respectively.



	18-24	25-34	35-44	45-54	≥ 55
Moderate dry eye	53.3	63.6	65.6	65.5	43.8
Severe dry eye	0	0	27.3	27.6	43.8

Figure 4.5 Prevalence of moderate and severe self-reported dry eye amongst the participants by age group

4.3.3 Prevalence of clinically diagnosed dry-eye

The clinical diagnosis of dry-eye is confirmed by a suitable test of tear production and the technique commonly used today to diagnose dry eye is the Schirmer's test (ST). Although the ST is easy to perform it gives variable results, poor reproducibility and low sensitivity for detecting dry eyes. Another test, the tear break-up time (TFBUT) is used to assess the stability of tears which if abnormal may also cause symptomatic dry-eye.

Figure 4.5 The difference between the quality and the quantity of the tears amongst the participants using TBU and schiemer tests

	TFBUT n (%)	Schirmer n (%)	p-value
Left Eye			
Normal Moderate Severe	8 (3.4) 162 (68.6) 66 (28.0)	136 (57.6) 49 (20.8) 51 (21.6)	<0.001
Right Eye			
Normal Moderate Severe	18 (.6) 161 (68.2) 57 (24.2)	131 (55.5) 66 (28.0) 39 (16.5)	<0.001

Table 4.6 The quality of the tears in the left and right eyes amongst the participants using TFBUT

		Quality of the tears – TFBUT Left eye				Quality of the tears – TFBUT Right eye			
		Normal	**Moderate**	**Severe**	**P-value for trend**	**Normal**	**Moderate**	**Severe**	**P-value for trend**
		n (%)	n (%)	n (%)		n (%)	n (%)	n (%)	
		Females							
Age in years									
	18-24	2 (9.5)	19 (90.5)	0 (0.0)		2 (9.5)	19 (90.5)	0 (0.0)	
	25-34	1 (2.9)	29 (82.9)	5 (14.3)	<0.001	2 (5.7)	26 (74.3)	7 (20.0)	0.053
	35-44	1 (2.1)	37 (78.7)	9 (19.2)		2 (4.3)	38 (80.9)	7 (14.9)	
	45-54	0 (0.0)	15 (62.5)	9 (37.5)		1 (4.2)	17 (70.8)	6 (25.0)	
	≥ 55	0 (0.0)	6 (37.5)	10 (62.5)		3 (18.8)	7 (43.8)	6 (37.5)	
		Males							
Age in years		n (%)	n (%)	n (%)		n (%)	n (%)	n (%)	
	18-24	4 (26.7)	10 (66.7)	1 (6.7)		4 (26.7)	11 (73.3)	0 (0.0)	
	25-34	0 (0.0)	8 (72.7)	3 (27.3)		0 (0.0)	8 (72.3)	3 (27.3)	
	35-44	0 (0.0)	15 (68.2)	7 (31.8)	<0.001	1 (4.6)	14 (63.6)	7 (31.8)	0.001
	45-54	0 (0.0)	19 (65.5)	10 (34.5)		2 (6.9)	18 (62.1)	9 (31.0)	
	≥ 55	0 (0.0)	4 (25.0)	12 (75.0)		1 (6.3)	3 (18.8)	12 (75.0)	

Table 4.6 above presents that the comparison between the quality of the tears for both the left and right eyes of the participants. It was found that females had statistical significant difference in the quality of the tears in the left eye looking at the age groups wherein majority of the participants were at the level of moderate in relation to tear quality. In relation to the moderate dry eye, the prevalence has decreased with increasing age which is contrary to the overall prevalence of dry in the current study. The prevalence of moderate dry eye has decreased from 90.5% in age group 18 – 24 years to 82.9% in age group 25 – 34 years followed by 78.9%, 62.5% and 37.5% in age groups 35 – 44 years, 45 – 54 years and greater or equal to 55 years respectively. However, in the right eye there was no statistical significance difference between the age groups amongst females. The prevalence of severe dry eye disease has shown a different trend from the moderate dry eye diseases as the prevalence has been increasing with increasing age from 14.3# in age group 25 – 34 years to 62.5% in age group 55 years and above. But in males there was statistical significance difference at $p<0.001$

Table 4.7 The quantity of the tears in the left and right eyes amongst the participants using Schiemer's tests

		Quantity of the tears – Schirmer's test Left eye				Quantity of the tears – Schirmer's test Right eye			P-value for trend
		Normal	**Moderate**	**Severe**	**P-value for trend**	**Normal**	**Moderate**	**Severe**	
		n (%)	n (%)	n (%)		n (%)	n (%)	n (%)	
Age in years									
	18-24	21 (100.0)	0 (0.0)	0 (0.0)		21 (100.0)	0 (0.0)	0 (0.0)	
	25-34	22 (62.9)	12 (34.3)	1 (2.9)	<0.001	23 (65.7)	11 (31.4)	1 (2.9)	<0.001
	35-44	33 (70.2)	9 (19.2)	5 (10.6)		30 (63.8)	14 (29.8)	3 (6.4)	
	45-54	12 (50.0)	6 (25.0)	6 (25.0)		11 (45.8)	7 (29.2)	6 (25.0)	
	≥ 55	4 (25.0)	4 (25.0)	8 (50.0)		5 (31.3)	6 (37.5)	5 (31.3)	
Age in years		n (%)	n (%)	n (%)		n (%)	n (%)	n (%)	
	18-24	15 (100.0)	0 (0.0)	0 (0.0)		13 (86.7)	2 (13.3)	0 (0.0)	
	25-34	7 (63.6)	2 (18.2)	2 (18.2)		7 (63.6)	2 (18.2)	2 (18.2)	
	35-44	11 (50.0)	4 (18.2)	7 (31.8)	<0.001	10 (45.5)	7 (31.8)	5 (22.7)	0.002
	45-54	11 (37.9)	7 (24.1)	11 (37.9)		10 (34.5)	10 (34.5)	9 (31.0)	
	≥ 55	0 (0.0)	5 (31.3)	11 (68.8)		1 (6.3)	7 (43.8)	8 (50.0)	

Table 4.7 above presents that the comparison between the quantity of the tears for both the left and right eyes of the participants. It was found that both males and females had statistical significant difference in the quantity of the tears in both the left and right eyes. The moderate dry eye using the measure of the quantity of the tears has decreased with increasing age in females using Schimer test for the left eye but in the right eyes it has been increasing with increasing age. In males an increasing trend of moderate dry eyes has been recorded in both left and right eyes. The prevalence of severe dry eye disease has shown an increasing trend in both males and females for both left and right eyes.

4.4 The determinants of dry eye

Table 4.8 below revealed that the risk of the dry eye disease in the current study was found significantly increasing with old age as those who were older (35 years above) were 4.2 times more likely to develop dry eye disease at *p-value <0.001* as compared to young participants. Those at age group 45 – 54 years and 55 years and above were found to be 9.8 and 11.9 times more likely to develop dry eye disease as compared to those who were in the age group 35 – 44 years at *p-value <0.001 and 0.002* respectively. Female gender was found not to be protective of developing dry eye disease in the current study but this was not statistically significant. Participants who were single were found to be 0.25 times less likely to develop dry eye diseases as compared to married participants at *p-value <0.001*. Participants with secondary educational level and tertiary educational level were found to be 2.3 and 3.6 times more likely to develop dry eye disease as compared to participants with no educational level or those with primary educational level at *p-value = 0.018 and 0.012* respectively. Lastly, participants with ocular conditions were 1.4 times more likely to develop dry eye disease at *p-value 0.006* and those with systemic disease were 7.2 times more likely to develop dry disease at *p-value 0.001*. Participants with surgery were 4.5 times more likely to develop dry disease at *p-value 0.006*. Participants with high blood pressure were 6.9 times more likely to develop dry disease at *p-value 0.002*.

Table 4.8**:** Univariate logistic regression to determine participant's demographics associated with dye eye

Univariate Logistic Regression		
	OR(95%CI)	p-value
Age in years		
18 – 34	Ref	
Older	4.2 (2.1 – 8.2)	<0.001
Age group in years		
18-24	Ref	
25-34	2.3 (0.9 – 5.7)	0.085
35-44	4.2 (1.7 – 10.6)	0.002
45-54	9.8 (2.9 – 32.9)	<0.001
≥ 55	11.9 (2.5 – 57.5)	0.002
Gender		
Males	Ref	
Females	1.1 (0.56 – 2.10)	0.804
Marital status		
Married	Ref	
Single	0.25 (0.12 – 0.50)	<0.001
Divorced	0.45 (0.05 – 4.47)	0.509
Widowed	–	–
Level of education		
None or Primary	Ref	
Secondary	2.3 (0.6 – 6.5)	0.018
Tertiary	3.6 (1.3 – 10.1)	0.012
Ocular condition		
No	Ref	
Yes	1.4 (1.1 – 1.8)	0.006
Ocular condition		
None	Ref	
Cataract	–	–
Glaucoma	–	–
Surgery	4.5 (1.5 – 13.5)	0.006
Cataract and wearing spectacles or had surgery	1.6 (0.2 – 14.0)	0.677
Systemic disease		
No	Ref	
Yes	7.2 (2.2 – 23.6)	0.001
Type of systematic diseases		
None	Ref	
High BP	6.9 (2.1 – 23.3)	0.002
Diabetes	–	–
High BP and Diabetes	–	–

Table 4.9 below presents the predictors of dry eye disease using multivariate logistic regression. Therefore, the findings of the current study show that older people who had systematic disease were 0.14 times less likely to develop dry eye disease at *p*-

value <0.001 while those participants who experienced foreign body sensation in their eyes were 11.3 times more likely to develop dry eye disease as compared to young participants who also experienced foreign body sensation in their eyes. There was a significant association between age and those participants who had sensitivity to light, feeling gritty, those who had poor vision, those who had blurred vision and those who had ocular condition. Older participants and having sensitivity to light and those who had uncomfortable feeling of having sand in the eye (feeling gritty) were 11.3 and 24.7 times more likely to develop dry eye disease. Those who were old and had poor vision and those who had blurred vision were 13.6 and 12.5 times more likely to develop dry eye disease. Participants who were old and having ocular condition were 1.3 times more likely to develop dry eye disease as compared to those who did not have ocular condition.

Female participants who had systematic disease were 8.4 times more likely to develop dry eye disease at *p-value <0.001* while those female participants who experienced foreign body sensation in their eyes were 13.3 times more likely to develop dry eye disease as compared to male participants who also experienced foreign body sensation in their eyes. There was also a significant association between gender and those participants who had sensitivity to light, feeling gritty, those who had poor vision, those who had blurred vision and those who had ocular condition. Female participants and having sensitivity to light and those who were feeling gritty in the eyes were 11.3 and 27.5 times more likely to develop dry eye disease as compared to male participants with same eye characteristics. Female participants who had poor vision and those who had blurred vision were 15.4 and 14.3 times more likely to develop dry eye disease as compared to male participants and those who had ocular condition were 1.4 times more likely to develop dry eye disease as compared to those who did not have ocular condition.

Participants who had low educational level and had systematic disease were 8.7 times more likely to develop dry eye disease at *p-value <0.005* while those participants who had low educational level and experienced foreign body sensation in their eyes were 13.4 times more likely to develop dry eye disease as compared to participants who had high educational level and also experienced foreign body sensation in their eyes. Similar findings were observed in educational status as there

was also a significant association between low educational level and those participants who had sensitivity to light, feeling gritty, those who had poor vision, those who had blurred vision and those who had ocular condition. Participants with low educational level and having sensitivity to light and those who were feeling gritty in the eyes were 10.4 and 27.4 times more likely to develop dry eye disease as compared to participants with higher educational level and same eye characteristics. Again participants who had low educational level coupled with poor vision and those who had blurred vision were 16.5 and 15 times more likely to develop dry eye disease as compared to with higher educational level and same eye characteristics while those who had ocular condition were 1.3 times more likely to develop dry eye disease as compared to those who did not have ocular condition.

Participants who were not married and had systematic disease were 8.1 times more likely to develop dry eye disease at *p-value <0.005* while those participants who not married and experienced foreign body sensation in their eyes were 12.6 times more likely to develop dry eye disease as compared to participants who were married and also experienced foreign body sensation in their eyes. There was also a significant association between marital status and those participants who had sensitivity to light, feeling gritty, those who had poor vision, those who had blurred vision and those who had ocular condition. Participants who were not married and having sensitivity to light and those who were feeling gritty in the eyes were 9.9 and 27 times more likely to develop dry eye disease as compared to participants who were married and same eye characteristics. Again participants who were not married coupled then had poor vision and those who had blurred vision were 13.6 and 12.9 times more likely to develop dry eye disease as compared to with participants who were married and same eye characteristics while those who had ocular condition were 1.4 times more likely to develop dry eye disease as compared to those who did not have ocular condition.

Participants who were not working and had systematic disease were 9.5 times more likely to develop dry eye disease at *p-value <0.001* while those participants who not working and experienced foreign body sensation in their eyes were 12.3 times more likely to develop dry eye disease as compared to participants who were working and also experienced foreign body sensation in their eyes. There was again a significant

association between work status and those participants who had sensitivity to light, feeling gritty, those who had poor vision, those who had blurred vision and those who had ocular condition. Participants who were not working and having sensitivity to light and those who were feeling gritty in the eyes were 9.6 and 26.2 times more likely to develop dry eye disease as compared to participants who were working and had same eye characteristics. Again participants who were not working then had poor vision and those who had blurred vision were 14 and 13.4 times more likely to develop dry eye disease as compared to with participants who were working and had same eye characteristics while those who had ocular condition were 1.3 times more likely to develop dry eye disease as compared to those who did not have ocular condition at $p\text{-}value<0.05$.

Table 4.9**:** Multivariate logistic regression to determine predictors of dye eye amongst study participants

Variables		**Systematic disease**	**Foreign body sensation**	**Sensitivity to light**	**Feeling gritty**	**Poor vision**	**Blurred vision**	**Ocular condition**
Age in years								
	18 – 34	Reference (1)	Reference (1)	Reference (1)	Reference (1)	Reference (1)	Reference (1)	Reference (1)
	≥35	0.14 (0.03 – 0.26)**	11.3 (5.2 – 24.7)***	8.9 (4.4 – 18.2)***	24.7 (5.8 – 43.8)***	13.6 (6.2 – 29.9)***	12.5 (5.8 – 26.9)***	1.3 (1.0 – 1.7)*
Gender								
	Male	Reference (1)	Reference (1)	Reference (1)	Reference (1)	Reference (1)	Reference (1)	Reference (1)
	Female	8.4 (2.5 – 28.2)**	13.3 (6.3 – 28.2)***	11.3 (5.4 – 23.6)***	27.5 (6.4 – 98.7)***	15.4 (7.1 – 33.2)***	14.3 (6.7 – 30.5)***	1.4 (1.1 – 1.8)***
Educational status								
	High	Reference (1)	Reference (1)	Reference (1)	Reference (1)	Reference (1)	Reference (1)	Reference (1)
	Low	8.7 (2.5 – 30.1)**	13.4 (6.3 – 28.5)***	10.4 (5.1 – 21.1)***	27.4 (6.5 – 76.9)***	16.5 (7.5 – 36.3)***	15.0 (7.0 – 32.4)***	1.3 (1.1 – 1.8)*
Marital status								
	Married	Reference (1)	Reference (1)	Reference (1)	Reference (1)	Reference (1)	Reference (1)	Reference (1)
	Not married	8.1 (2.4 – 27.9)**	12.6 (5.8 – 27.3)***	9.9 (4.9 – 20.2)***	27.0 (63 – 87.9)***	13.6 (6.3 – 29.5)***	12.9 (6.0 – 27.4)***	1.4 (1.1 – 1.8)*
Work status								
	Working	Reference (1)	Reference (1)	Reference (1)	Reference (1)	Reference (1)	Reference (1)	Reference (1)
	Not working	9.5 (2.8 – 32.6)***	12.3 (5.8 – 26.4)***	9.6 (4.8 – 19.7)***	26.2 (6.2 – 67.9)***	14.0 (6.4 – 30.7)***	13.4 (6.1 – 29.2)***	1.3 (1.0 – 1.7)*

Values are reported as odds ratios (95%CI); * significant *at p<0.05;* ** significant *at p<0.005;* *** significant *at p<0.001*, [a]Not significant

5 CHAPTER 5: DISCUSSION AND CONCLUSION

5.3 Introduction

In the previous chapter, the findings of this study were presented and interpreted. In this chapter, the results of this study are discussed and compared to the relevant literature. The chapter is divided into the following sub-sections: (1) introduction, (2) Socio-demographic characteristics of participants, (3) prevalence of dry eye disease and (4) the determinants of dry eye diseases, (5) study limitations, (6) conclusion and (7) recommendation.

5.4 Socio-demographics of patients who took part in this study

The current study findings revealed that the mean age of the participants was 39.7 ± 13.7 years which is similar to a study conducted in Singapore (Tan, Morgan, Cai & Straughan, 2015). Majority of participants were females and there was a statistical significance difference in age groups of both males and females at *p-value=0.011* which concurs with the study findings of a study conducted in Ontario, Canada in which majority of the participants were also females (Caffery et al., 2019). The current study findings concur with study findings from a study by Farrand et al., (2017) as majority of the participants were married followed by those who were single and divorced respectively. In the Farrand et al., (2017) study, the difference in marital status showed a statistical significance difference which differs with the findings from the current study.

5.5 Prevalence of dry eye

The outcome of the current study shows that 80.9% 0f South Africans aged 18 years and older residing in Kwa Mhlanga had DED. Symptoms of discomfort and ocular damages are known to be related to tear hyperosmolarity and ocular surface inflammation that are common major determinants of all forms of dry eye disease (Malet et al., 2014).

Dry eye is the disorder most frequently associated with filamentary keratitis which is is generally a chronic corneal condition, characterized by fine strands of degenerated epithelial cells and mucus attached to the cornea at one or both ends (Wolffsohn, Arita, Chalmers, Djalilian, Dogru & Dumbleton et al., 2017). The

subjective symptoms in dry eye disease are often nonspecific and they include redness, burning, stinging, foreign body sensation, pruritus, grittiness, discomfort and photophobia which are similar to signs experienced with filamentary keratitis (Messmer, 2015; Wolffsohn et al., 2017; Voss, Nguyen & Heur, 2021).

In the current study, majority of the participants have reported to have foreign body sensation sometimes and experience of sensitivity to bright light which differs from the study findings in a study conducted among Japanese visual display terminal (VDT) workers (Kawashima, Yamatsuji, Yokoi, Fukui, Ichihashi & Kato et al., 2015). The greater difference might be due to the fact the Japanese study was conducted amongst visual display terminal as compared to general patients who were consulting in an optometry surgery in the current study. The current study concurs with a study conducted in study was conducted in Moriguchi town, Osaka, Japan as participants who had foreign body sensation sometimes were approximately 51% (Kaido, Uchino, Yokoi, Uchino, Dogru & Kawashima et al., 2014.) as is the case in this study. However, those participants who were experiencing sensitivity to bright light were 47.8% which is lower than the findings in the current study of 53.8% (Kaido et al., 2014).

The current study findings revealed that approximately 39% of the participants reported to have feeling gritty in their eyes and 21% complained of soreness in the eyes which is more that findings in a study conducted in western Maharashtra, India as only 20% and 29% of the participants complained of grittiness and soreness in the eyes in the eyes respectively (Bhatnagar, Pote, Pujari & Deka, 2015). In the current study, majority of participants (76%) reported to be having poor vision and blurred vision which is higher than the 67% reported in a study conducted in conducted in Moriguchi town, Osaka, Japan (Kaido et al., 2014). The current study findings are also in contrary to the findings by Eiyue et al (2016) in Singapore as only 40% of the participants reported symptoms of blurred vision while 50% reported symptoms of irritation and 25% reported symptoms of photophobia (Liyue, Chiang, Sung & Tong, 2016)

Epidemiologic studies reveal that dry eye disease has a prevalence ranging from 7.8% to 14.6% in the United States (Williamson, Huynh, Weaver & Davis, 2014).

In the general adult population, the exact prevalence of dry eye disease is not known and has been crudely estimated between 6 and 34% (Malet et al., 2014). These findings are extremely different from the findings for the current study as the prevalence of dry eye in the current study was found to be 80.9%. This might be due to the difference in the wide presentation of non-specific ocular symptoms as in this study the focus was on six (6) symptoms which are foreign body sensation, sensitivity to light, feeling gritty, painful or sore eyes, poor vision and blurred vision. Secondly, the participants in the current study were patients consulting at eye clinic which could have contributed to the high prevalence of dry eye disease in the current study.

This condition dry eye disease is one of the most common reasons why patients visits eye care professionals. It is also challenging to define due to a wide spectrum of abnormalities to the ocular surface and a variety of presenting symptoms that can change from day to day and from patient to patient (Jackson, 2009; Zeev, Miller & Latkany, 2014). Patients who have dry eye often complain of eye irritation, a gritty or foreign body sensation, burning, tearing, photophobia, stinging, or intermittent sharp pain (Zeev et al., 2014; Goldstein & Rao, 2018; Mehra, Cohen & Galor, 2020). Blurry vision that improves with blinking or instillation of non-viscous artificial tears, albeit temporarily, is also common. Dry eye patients may have all, some, or none of these symptoms (Mehra et al., 2020).

Dry eye disease is known to increase with age (Dana, Bradley, Guerin, Pivneva, Stillman & Evans et al., 2019) and the prevalence estimates of dry eye disease range from 5% to 34% in individuals over 50 years old (Malet et al., 2014; Dana et al., 2019). This concurs with the findings from the current study as the overall prevalence of dry eye disease in the current study by gender has shown to be increasing with age. However, the overall prevalence has been very high in the current study and this could be attributed to the differences in definition of dry eye and methodology among studies (Dana et al., 2019).

In the current study, the prevalence of moderate dry eyes was found to be 58.5% as compared to 22.4% of severe dry eyes. These findings differ from the findings

of a study conducted amongst post-menopausal women visiting a hospital as only 8% had moderate and 3% had severe dry eyes (Agarwal, Singh, Rajpal, Kumar, Raghuwanshi & Ramnani, 2016). However, in a study conducted in Karnataka, India the prevalence of moderate dry eye was found in 33.0%, severe dry eye in 11.5% (Shaikh & Ameen, 2015). The similarity with the current study findings and other studies is that the prevalence of moderate dry eye disease has been higher than the severe dry eye disease.

Symptoms alone are inadequate for the diagnosis of dry eye (Masmali, Purslow & Murphy, 2014), because the same symptoms can be experienced with a range of ocular surface conditions and tear film disorders (Sambursky, Davitt III, Friedberg & Tauber, 2014). Tears play an important role in maintaining the health of the ocular surface and tears contain essential components associated with the regulation of proliferation, differentiation, and maturation of ocular surface epithelia, including epidermal growth factors, vitamin A, hepatocyte growth factor, fibronectin, and neurotrophic growth factor (Celebi, Ulusoy & Mirza, 2014). A healthy tear film is very important for many major functions of the ocular surface and dry eye disease is a significant clinical problem that needs to be solved. However, the poor correlation between clinical signs and reported symptoms makes it difficult for the clinician to apply a scientific basis to his clinical management (Masmali et al., 2014).

The clinical diagnosis of dry-eye is confirmed by a suitable test of tear production and the technique commonly used today to diagnose dry eye is the Schirmer's test (ST). Although the ST is easy to perform it gives variable results, poor reproducibility, lacks standardization and low sensitivity for detecting dry eyes. Another test, the tear break-up time (TFBUT) is used to assess the stability of tears which if abnormal may also cause symptomatic dry-eye (Sambursky et al., 2014).

Patients with conditions of uncertain etiology represent challenges to nearly all medical specialties, and the treatment of dry eye disease (DED) has been a prominent subject of ongoing debate in ophthalmology (Shtein, Harper, Pallazola, Harte, Hussain & Sugar et al., 2016). The quantity and quality of the tear film

composition are important for maintaining the ocular surface and good vision. Absence or degeneration in the quantity and/or quality of the tear film leads to a chronic tear film problem and ultimately, dry eye (Masmali et al., 2014).

TFBUT checks the quality rather than the quantity of tear film. Because the Schirmer's test checks the quantity and TFBUT mainly checks the quality of tear film, the lack of alignment of their changes could be explained. Although Schirmer's test is less sensitive than TFBUT for the dry eye diagnosis and doesn't show acute tear film dysfunction as well as TFBUT test does, Schirmer's test is valuable for assessing the long-term sequels of ocular surface diseases such as dry eye syndrome (Makateb & Torabifard, 2017).

5.6 The determinants of dry eye

DED has two closely inter related underlying pathophysiologic mechanisms. These include tear hyperosmolarity which could result from low aqueous flow or excessive evaporation, and tear film instability which could be a primary event or secondary to underlying tear hyperosmolarity (Onwubiko, Eze, Udeh, Arinze, Onwasigwe & Umeh, 2014). In the current study, dry eye disease was significantly associated with older age which concurs with a study by Onwubiko et al (2014) conducted in Nigeria. This probably reflects the normal age-related reduction in tear production, alterations in tear film characteristics and tear dynamics, and increased evaporative tear loss. Gender was not significantly associated with dry eye disease in the current study which also concurs with a study conducted in Nigeria (Onwubiko et al 2014). However, in a study conducted in it was found that the risk of Diagnosed-DED was 2-fold higher among women than men (Garg, Gupta & Nishi Tandon, 2020) which differs from the findings of the current study.

The current study revealed that ocular conditions and systemic disease were significantly associated with the development of dry disease. The study further reported that surgery was significantly associated with the development of dry disease which concurs with a study conducted in Singapore (Teo, Ong, Liu & Tong, 2020). In the current study high blood pressure was significantly associated with dry disease which is in disagreement with a study conducted in

Saudi Arabia which reported that hypertension to DED were not statistically significant however the current study concurs with this study by reporting that diabetes was not associated with dry eye disease (Yasir, Chauhan, Khandekar, Souru & Varghese, 2019)

5.7 Study limitations

The limitations of the current study were that it was not possible to correlate the subjective and objective measures of diagnosis for dry eye disease. The participants were patients who were consulting at eye clinic which could have contributed to the high prevalence of dry eye disease in the current study.

5.8 Conclusion

In conclusion it was found that dry eye disease in more prevalent in the current study and it was significantly associated with increasing age. Dry eye disease was significantly associated with older age, ocular conditions and systemic disease but not associated with gender. To the best of our knowledge this is the first report correlating the grades of DED to the usual disability in Kwa Mhlanga. The information will also assist in improving eye care not only in this study but also other areas with weather conditions.

5.9 Recommendations

5.9.1 *Policies*

These findings suggest the need for targeted interventions for general population to screen for dye eye disease with an aim to prevent complications and reduce determinants of dry eye disease at young age.

5.9.2 *Health facilities*

Questionnaires are valuable tools for symptom screening that can capture the patient's experience and be easily implemented in everyday practice. Furthermore, they can detect subclinical and unrecognizable cases of dry eye, which is especially important in patients who are planned to undergo high visual expectation ophthalmic surgeries. Therefore, public health facilities should be recommended to use questionnaires to screen for dry eye

diseases. These could be self-administered questionnaires as public health facilities have limited human resources and increased competing interests in providing health care services.

5.9.3 *Research*

Dry eye disease is a major public health problem whose burden is likely to increase due to the increasing proportion of the aging population and adoption of modern lifestyles. Due to competing research resource needs from the major blinding eye diseases like cataract, glaucoma, and age-related macular degeneration, dry eye disease remains an under-researched condition in South Africa like other low- and middle-income countries (LMICs). Therefore, more epidemiological studies have to be conducted at population and health facility level across all ages. Lastly, the most widely used signs of dry eye disease are poorly correlated with each other and with symptoms. While symptoms are thought to be characteristic of DED, recent studies have shown that less than 60% of subjects with other objective evidence of DED are symptomatic. Thus the use of symptoms alone in diagnosis will likely result in missing a significant percentage of DED patients, particularly with early/mild disease. This could have considerable impact in patients undergoing cataract or refractive surgery as patients with DED have less than optimal visual results. Therefore, correlation studies are needed.

5.8. Contributions of the study and implications for healthcare

This study will contribute in the body of knowledge, and will assist the policymakers to make evidence-based decisions during allocation of the healthcare resources, including prevention and treatment strategies related to dry eye diseases.

REFERENCES

Abetz, L., Rajagopalan, K., Mertzanis, P., Begley, C., Barnes, R., Chalmers, R. and Impact of Dry Eye on Everyday Life (IDEEL) Study Group, 2011. Development and validation of the impact of dry eye on everyday life (IDEEL) questionnaire, a patient-reported outcomes (PRO) measure for the assessment of the burden of dry eye on patients. *Health and Quality of life Outcomes*, *9*(1), p.111.

Agarwal, R., Singh, P., Rajpal, T., Kumar, R., Raghuwanshi, S. and Ramnani, V., 2016. Hospital based study of prevalence of dry eye in post-menopausal women. *Indian Journal of Clinical and Experimental Ophthalmology*, *2*(1), pp.56-61.

Aguilar, A.J., Marquez, M.I., Albera, P.A., Tredicce, J.L. and Berra, A., 2014. Effects of Systane® Balance on noninvasive tear film break-up time in patients with lipid-deficient dry eye. *Clinical ophthalmology (Auckland, NZ)*, *8*, p.2365.

Alshamrani, A.A., Almousa, A.S., Almulhim, A.A., Alafaleq, A.A., Alosaimi, M.B., Alqahtani, A.M., Almulhem, A.M., Alshamrani, M.A., Alhallafi, A.H., Alqahtani, I.Z. and Alshehri, A.A., 2017. Prevalence and risk factors of dry eye symptoms in a Saudi Arabian population. *Middle East African journal of ophthalmology*, *24*(2), p.67.

Alves, M., Novaes, P., Morraye, M.D.A., Reinach, P.S. and Rocha, E.M., 2014. Is dry eye an environmental disease?.*Arquivosbrasileiros de oftalmologia*, *77*(3), pp.193-200.

Alves, M., Reinach, P.S., Paula, J.S., e Cruz, A.A.V., Bachette, L., Faustino, J., Aranha, F.P., Vigorito, A., de Souza, C.A. and Rocha, E.M., 2014. Comparison of diagnostic tests in distinct well-defined conditions related to dry eye disease. *PloS one*, *9*(5)

Artal, P., 2015. Image formation in the living human eye.

Bartlett, J.D., Keith, M.S., Sudharshan, L. and Snedecor, S.J., 2015. Associations between signs and symptoms of dry eye disease: a systematic review. *Clinical Ophthalmology (Auckland, NZ)*, *9*, p.1719.

Baudouin, C., Aragona, P., Van Setten, G., Rolando, M., Irkeç, M., del Castillo, J.B., Geerling, G., Labetoulle, M. and Bonini, S., 2014. Diagnosing the severity of dry eye: a clear and practical algorithm. *British Journal of Ophthalmology*, *98*(9), pp.1168-1176.

Bhatnagar, K.R., Pote, S., Pujari, S. and Deka, D., 2015. Validity of subjective assessment as screening tool for dry eye disease and its association with clinical tests. *International journal of ophthalmology*, *8*(1), p.174.

Botma, Y, Greeff,M, Mulaudzi, F.M.& Wright,S.C.D.,2010, Research in Health Sciences**,** Pearson Education, South Africa.

Bron, A.J., Tomlinson, A., Foulks, G.N., Pepose, J.S., Baudouin, C., Geerling, G., Nichols, K.K. and Lemp, M.A., 2014. Rethinking dry eye disease: a perspective on clinical implications. *The ocular surface*, *12*(2), pp.S1-S31.

Caffery, B., Srinivasan, S., Reaume, C.J., Fischer, A., Cappadocia, D., Siffel, C. and Chan, C.C., 2019. Prevalence of dry eye disease in Ontario, Canada: a population-based survey. *The ocular surface*, *17*(3), pp.526-531.

Castelyn, B., Majola, S., Motilal, R., Naidu, M.T., Ndebele, S.A., Vally, T.A., Khan, N.E. and Khan, N., 2015. Prevalence of dry eye amongst black and Indian university students aged 18–30 years. *Eye*, *74*, p.1.

Celebi, A.R.C., Ulusoy, C. and Mirza, G.E., 2014. The efficacy of autologous serum eye drops for severe dry eye syndrome: a randomized double-blind crossover study. *Graefe's archive for clinical and experimental ophthalmology*, *252*(4), pp.619-626.

Cetinkaya, S., Mestan, E., Acir, N.O., Cetinkaya, Y.F., Dadaci, Z. and Yener, H.I., 2015. The course of dry eye after phacoemulsification surgery. *BMC ophthalmology*, *15*(1), p.68.

Cioffi, C.L., 2020. Introduction: Overview of the Human Eye, Mammalian Retina, and the Retinoid Visual Cycle.

Cooper, H., Hedges, L.V. and Valentine, J.C. eds., 2019. *The handbook of research synthesis and meta-analysis*. Russell Sage Foundation.

Cornec, D., Saraux, A., Jousse-Joulin, S., Pers, J.O., Boisramé-Gastrin, S., Renaudineau, Y., Gauvin, Y., Roguedas-Contios, A.M., Genestet, S., Chastaing, M. and Cochener, B., 2015. The differential diagnosis of dry eyes, dry mouth, and parotidomegaly: a comprehensive review. *Clinical reviews in allergy & immunology*, *49*(3), pp.278-287.

Creswell, John. W. and Creswell, J. David. 2018. Research Design, fifth edition, Qualitative, Quantitative, and Mixed Methods Approaches.

Dana, R., Bradley, J.L., Guerin, A., Pivneva, I., Stillman, I.Ö., Evans, A.M. and Schaumberg, D.A., 2019. Estimated prevalence and incidence of dry eye disease based on coding analysis of a large, all-age United States health care system. *American journal of ophthalmology*, *202*, pp.47-54.

Dattalo, P., 2013. *Analysis of multiple dependent variables*. Oxford University Press.
de França, C.F.S.M., de Lima Fernandes, A.P.N., Pinto, D.P.D.S.R., de Mesquita Xavier, S.S., Júnior, M.A.F., Botarelli, F.R. and Vitor, A.F., 2016. Evidence of interventions for the risk of dry eye in critically ill patients: an integrative review. *Applied Nursing Research*, *29*, pp.e14-e17

de Kluizenaar, Y., Roda, C., Dijkstra, N.E., Fossati, S., Mandin, C., Mihucz, V.G., Hänninen, O., de Oliveira Fernandes, E., Silva, G.V., Carrer, P. and Bartzis, J., 2016. Office characteristics and dry eye complaints in European workers–The OFFICAIR study. *Building and Environment*, *102*, pp.54-63.

Denoyer, A., Landman, E., Trinh, L., Faure, J.F., Auclin, F. and Baudouin, C., 2015. Dry eye disease after refractive surgery: comparative outcomes of small incision lenticule extraction versus LASIK. *Ophthalmology*, *122*(4), pp.669-676.

Epstein, A.B., Karpecki, P.M., Mastrota, K.M. and Whitley, W.O., 2016. Dry eye disease: what we know about it today and its importance for optometry. *Review of Optometry*, *153*(5), pp.S1-S1.

Ervin, A.M., Law, A. and Pucker, A.D., 2017. Punctal occlusion for dry eye syndrome. *Cochrane Database of Systematic Reviews*, (6).

Farrand, K.F., Fridman, M., Stillman, I.Ö. and Schaumberg, D.A., 2017. Prevalence of diagnosed dry eye disease in the United States among adults aged 18 years and older. *American journal of ophthalmology*, *182*, pp.90-98.

Foulks, G.N., Forstot, S.L., Donshik, P.C., Forstot, J.Z., Goldstein, M.H., Lemp, M.A., Nelson, J.D., Nichols, K.K., Pflugfelder, S.C., Tanzer, J.M. and Asbell, P., 2015. Clinical guidelines for management of dry eye associated with Sjögren disease. *The ocular surface*, *13*(2), pp.118-132.

Galor, A., Feuer, W., Lee, D.J., Florez, H., Carter, D., Pouyeh, B., Prunty, W.J. and Perez, V.L., 2011. Prevalence and risk factors of dry eye syndrome in a United States veterans' affairs population. *American journal of ophthalmology*, *152*(3), pp.377-384.

Garg, P., Gupta, A. and Nishi Tandon, P.R., 2020. Dry eye disease after cataract surgery: study of its determinants and risk factors. *Turkish Journal of Ophthalmology*, *50*(3), p.133.

Gayton, J.L., 2009. Etiology, prevalence, and treatment of dry eye disease. *Clinical ophthalmology (Auckland, NZ)*, *3*, p.405

Gillan, W.D.H., 2009. A small-sample survey of dry eye symptoms using the Ocular Surface Disease Index. *African Vision and Eye Health*, *68*(4), pp.188-191.
Goldstein, M.H. and Rao, N.K., 2018. Dry Eye Disease. *Ophthalmology, 5th ed.;*

Yanoff, M., Duker, JS, Eds, p.272.

Heidari, M., Noorizadeh, F., Wu, K., Inomata, T. and Mashaghi, A., 2019. Dry eye disease: emerging approaches to disease analysis and therapy. *Journal of clinical medicine*, *8*(9), p.1439.

Hengartner, M.P., Kawohl, W., Haker, H., Rössler, W. and Ajdacic-Gross, V., 2016. Big Five personality traits may inform public health policy and preventive medicine: Evidence from a cross-sectional and a prospective longitudinal epidemiologic study in a Swiss community. *Journal of Psychosomatic Research*, *84*, pp.44-51.

Henrich, C.F., Ramulu, P.Y. and Akpek, E.K., 2014. Association of dry eye and inflammatory systemic diseases in a tertiary care–based sample. *Cornea*, *33*(8), pp.819-825.

Hessen, M. and Akpek, E.K., 2014. Dry eye: an inflammatory ocular disease. *Journal of ophthalmic & vision research*, *9*(2), p.240.
Jackson, W.B., 2009. Management of dysfunctional tear syndrome: a Canadian consensus. *Canadian Journal of Ophthalmology*, *44*(4), pp.385-394.

Kaido, M., Uchino, M., Yokoi, N., Uchino, Y., Dogru, M., Kawashima, M., Komuro, A., Sonomura, Y., Kato, H., Kinoshita, S. and Tsubota, K., 2014. Dry-eye screening by using a functional visual acuity measurement system: the Osaka Study. *Investigative ophthalmology & visual science*, *55*(5), pp.3275-3281.

Karampatakis, V., Karamitsos, A., Skriapa, A. and Pastiadis, G., 2010. Comparison between normal values of 2-and 5-minute Schirmer test without anesthesia. *Cornea*, *29*(5), pp.497-501)

Kawashima, M., Yamatsuji, M., Yokoi, N., Fukui, M., Ichihashi, Y., Kato, H., Nishida, M., Uchino, M., Kinoshita, S. and Tsubota, K., 2015. Screening of dry eye disease in visual display terminal workers during occupational health examinations: The Moriguchi study. *Journal of occupational health*, *57*(3), pp.253-258.

Kels, B.D., Grzybowski, A. and Grant-Kels, J.M., 2015. Human ocular anatomy. *Clinics in dermatology*, *33*(2), pp.140-146.

Khan, M.W., Tareen, A.K. and Sultan, I.N., 2016. Ethics in Public Health Research and Clinical Research. *Bangladesh Journal of Bioethics*, *7*(2), pp.25-30.

Leavy, P., 2017. *Research design: Quantitative, qualitative, mixed methods, arts-based, and community-based participatory research approaches*. Guilford Publications.

Liyue, H., Chiang, P.P.C., Sung, S.C. and Tong, L., 2016. Dry eye-related visual blurring and irritative symptoms and their association with depression and anxiety in eye clinic patients. *Current eye research*, *41*(5), pp.590-599.

Louangrath, P., 2014. Sample size determination for non-finite population. *Southeast-Asian J. of Sciences*, *3*(2), pp.141-152.

Lu, F., Tao, A., Hu, Y., Tao, W. and Lu, P., 2018. Evaluation of reliability and validity of three common dry eye questionnaires in Chinese. *Journal of ophthalmology*, *2018*.

Makateb, A. and Torabifard, H., 2017. Dry eye signs and symptoms in night-time workers. *Journal of current ophthalmology*, *29*(4), pp.270-273

Malet, F., Le Goff, M., Colin, J., Schweitzer, C., Delyfer, M.N., Korobelnik, J.F., Rougier, M.B., Radeau, T., Dartigues, J.F. and Delcourt, C., 2014. Dry eye disease in French elderly subjects: theAlienor Study. *Actaophthalmologica*, *92*(6), pp.e429-e436.

Masmali, A.M., Purslow, C. and Murphy, P.J., 2014. The tear ferning test: a simple clinical technique to evaluate the ocular tear film. *Clinical and Experimental Optometry*, *97*(5), pp.399-406.

Meek, K.M. and Knupp, C., 2015. Corneal structure and transparency. *Progress in retinal and eye research*, *49*, pp.1-16.

Mehra, D., Cohen, N.K. and Galor, A., 2020. Ocular surface pain: a narrative review. *Ophthalmology and Therapy*, *9*, pp.1-21.

Mélard, G., On the accuracy of statistical procedures in Microsoft Excel 2010.

Messmer, E.M., 2015. The pathophysiology, diagnosis, and treatment of dry eye disease. *Deutsches Ärzteblatt International*, *112*(5), p.71.

Mostafa, E.M., 2016. Prevalence of dry eye disease in Southern Egypt: a hospital-based outpatient clinic study. *Journal of the Egyptian Ophthalmological Society*, *109*(1), p.32.

Nowak, M.S. and Smigielski, J., 2016. The Prevalence and Risk Factors for Dry Eye Disease among Older Adults in the City of Lodz, Poland. *Open Journal of Ophthalmology*, *6*(01), p.1.

Onua, A.A. and Chukwuka, I.O., 2017. Prevalence of dry eye disease in a rural Niger delta community, southern Nigeria. *Open Journal of Ophthalmology*, *7*(2), pp.95-102.

Onwubiko, S.N., Eze, B.I., Udeh, N.N., Arinze, O.C., Onwasigwe, E.N. and Umeh, R.E., 2014. Dry eye disease: prevalence, distribution and determinants in a hospital-based population. *Contact Lens and Anterior Eye*, *37*(3), pp.157-161.

Osae, A.E., Gehlsen, U., Horstmann, J., Siebelmann, S., Stern, M.E., Kumah, D.B. and Steven, P., 2017. Epidemiology of dry eye disease in Africa: the sparse information, gaps and opportunities. *The ocular surface*, *15*(2), pp.159-168.

Ousler III, G., Devries, D.K., Karpecki, P.M. and Ciolino, J.B., 2015. An evaluation of Retaine™ ophthalmic emulsion in the management of tear film stability and ocular surface staining in patients diagnosed with dry eye. *Clinical ophthalmology (Auckland, NZ)*, *9*, p.235.

Pan, Q., Angelina, A., Marrone, M., Stark, W.J. and Akpek, E.K., 2017. Autologous serum eye drops for dry eye. *Cochrane Database of Systematic Reviews*, (2).

Pannucci, CJ & Wilkins, EC. 2010. Identifying and Avoiding Bias in Research. *PlasticReconstructive Surgery* 126(2):619-625.

Paulsen, A.J., Cruickshanks, K.J., Fischer, M.E., Huang, G.H., Klein, B.E., Klein, R. and Dalton, D.S., 2014. Dry eye in the beaver dam offspring study: prevalence, risk factors, and health-related quality of life. *American journal of ophthalmology*, *157*(4), pp.799-806.

Phadatare, S.P., Momin, M., Nighojkar, P., Askarkar, S. and Singh, K.K., 2015. A comprehensive review on dry eye disease: diagnosis, medical management, recent developments, and future challenges. *Advances in Pharmaceutics*, *2015*.

Pinfield, S., Cox, A.M. and Smith, J., 2014. Research data management and libraries: Relationships, activities, drivers and influences. *PLoS One*, *9*(12).

Pucker, A.D., Ng, S.M. and Nichols, J.J., 2016. Over the counter (OTC) artificial tear drops for dry eye syndrome. *Cochrane Database of Systematic Reviews*, (2).

Ranjan, R., Shukla, S.K., Singh, C.V., Mishra, B.N., Sinha, S. and Sharma, B.D., 2016. Prevalence of Dry Eye and its Association with various risk factors in rural setup of Western Uttar Pradesh in a Tertiary care hospital. *Open Journal of Preventive Medicine*, *6*(01), p.57.

Sahai, A. and Malik, P., 2005. Dry eye: prevalence and attributable risk factors in a hospital-based population. *Indian journal of ophthalmology*, *53*(2), p.87.

Sambursky, R., Davitt III, W.F., Friedberg, M. and Tauber, S., 2014. Prospective, multicenter, clinical evaluation of point-of-care matrix metalloproteinase-9 test for confirming dry eye disease. *Cornea*, *33*(8), pp.812-818.

Senkubuge, F. and Mayosi, B.M., 2012. The state of the National Health Research system in South Africa: Leadership and governance. *South African health review*, *2012*(1), pp.141-149

Shaikh, R. and Ameen, J., 2015. Prevalence of dry eye disease in type 2 diabetic patients and its co-relation with the duration, glycemic control and retinopathy. *Al Ameen J Med Sci*, *8*(3), pp.225-9.

Shtein, R.M., Harper, D.E., Pallazola, V., Harte, S.E., Hussain, M., Sugar, A., Williams, D.A. and Clauw, D.J., 2016. Discordant dry eye disease (an American Ophthalmological Society thesis). *Transactions of the American Ophthalmological Society*, *114*.

Tan, L.L., Morgan, P., Cai, Z.Q. and Straughan, R.A., 2015. Prevalence of and risk factors for symptomatic dry eye disease in Singapore. *Clinical and Experimental Optometry*, *98*(1), pp.45-53.

Teo, C.H.Y., Ong, H.S., Liu, Y.C. and Tong, L., 2020. Meibomian gland dysfunction is the primary determinant of dry eye symptoms: Analysis of 2346 patients. *The Ocular Surface*, *18*(4), pp.604-612.

Terre Blanche,M.,Durrheim,K.& Painter,D.,2014,Research in practice: Applied method for the social sciences,Juta&Company Ltd.

Thygesen, L.C. and Ersbøll, A.K., 2014. When the entire population is the sample: strengths and limitations in register-based epidemiology. *European journal of epidemiology*, *29*(8), pp.551-558.

Tsubota, K., Yokoi, N., Shimazaki, J., Watanabe, H., Dogru, M., Yamada, M., Kinoshita, S., Kim, H.M., Tchah, H.W., Hyon, J.Y. and Yoon, K.C., 2017. New

perspectives on dry eye definition and diagnosis: a consensus report by the Asia Dry Eye Society. *The ocular surface*, *15*(1), pp.65-76.

Uchino, M., Nishiwaki, Y., Michikawa, T., Shirakawa, K., Kuwahara, E., Yamada, M., Dogru, M., Schaumberg, D.A., Kawakita, T., Takebayashi, T. and Tsubota, K., 2011. Prevalence and risk factors of dry eye disease in Japan: Koumi study. *Ophthalmology*, *118*(12), pp.2361-2367.

Vehof, J., Kozareva, D., Hysi, P.G. and Hammond, C.J., 2014. Prevalence and risk factors of dry eye disease in a British female cohort. *British Journal of Ophthalmology*, *98*(12), pp.1712-1717.

Voss, K., Nguyen, A. and Heur, M., 2021. Non-infectious and non-hereditary diseases of the corneal epithelium. *Experimental Eye Research*, *202*, p.108316.

Wei, Y. and Asbell, P.A., 2014. The core mechanism of dry eye disease (DED) is inflammation. *Eye & contact lens*, *40*(4), p.248.

Williamson, J.F., Huynh, K., Weaver, M.A. and Davis, R.M., 2014. Perceptions of dry eye disease management in current clinical practice. *Eye & contact lens*, *40*(2), p.111.

Wolffsohn, J.S., Arita, R., Chalmers, R., Djalilian, A., Dogru, M., Dumbleton, K., Gupta, P.K., Karpecki, P., Lazreg, S., Pult, H. and Sullivan, B.D., 2017. TFOS DEWS II diagnostic methodology report. *The ocular surface*, *15*(3), pp.539-574.

World Medical Association. 2013. *Declaration of Helsinki on Ethical Principle for Medical Research involving Human Subjects*. Brazil: Fortaleza.

Yasir, Z.H., Chauhan, D., Khandekar, R., Souru, C. and Varghese, S., 2019. Prevalence and determinants of dry eye disease among 40 years and older population of Riyadh (except capital), Saudi Arabia. *Middle East African journal of ophthalmology*, *26*(1), p.27

Zeev, M.S.B., Miller, D.D. and Latkany, R., 2014. Diagnosis of dry eye disease and emerging technologies. *Clinical Ophthalmology (Auckland, NZ)*, *8*, p.581.

Zucoloto, M.L., Maroco, J. and Campos, J.A.D.B., 2016. Impact of oral health on health-related quality of life: a cross-sectional study. *BMC Oral Health*, *16*(1), p.55.

APPENDICES

Annexure A: Data collection tool

Participant Unique Number:_____

Section A: Socio-Demographic Characteristics

1. Age in years_____

2. Gender Male [--] Female [--]

3. Educational Level

No Schooling	
Primary education	
Secondary education	
Tertiary education	

4. Marital status

Single/never married	
Married/co-habiting	
Divorced/separated	
Widowed	

5. Employment status

Working	
Not working	

Section B: Eye conditions

1. Have you done any eye surgery?

Yes	No

2. Have you ever consulted dry eyes?

Yes	No

3. If yes, are you taking any medication?
4. How often do you experience the following?

	Never	Occasionally	Frequently
Pain / Ache			
Itching			
Dryness			

Burning			
Tearing			

5. Have you been diagnosed with Glaucoma

6. If yes are you using and medications for Glaucoma?

7. Are you currently using any spectacles and or contact lenses?

8. If yes to no 7 above, list the medications

9. Are you using drying medications such as antidepressants, anxiolytics and antihistamines, or preservative-formulated eye drops

Section C: Other medical conditions

1. Do you have any chronic disease?

Yes	No

2. If yes which condition? <u>Tick in the box below</u>

Connective tissue diseases,	
Diabetes Mellitus,	
Systemic hypertension	
Arthritis	
Sjögren syndrome	
Vitamin A deficiency	
Ocular diseases like blephritis, chronic conjunctivitis, meibomitis, and pengueculapterygium	
Laser vision correction or cataract removal	

3. Are you taking medication?

Yes	No

4. Pregnancy

Yes	No

Menopause

Yes	No

Yes	No

5. Have you been diagnosed with any autoimmune disease?

Section D: Work environment

1. Do you work indoors?

Yes	No

1.1. If yes, Estimation hours per day for indoors_____

1.2. How many hours do you work on the computer, laptop and Smartphone? Hours per day_____

2. Do you work in an air conditioned environment?

Yes	No

3. Do you wear spectacles to work indoors?

Yes	No

4. Do you work outdoors?

Yes	No

4.1. If yes, How many hours per day_____

4.2. Do you work in an air sunny or dusty environment?

Yes	No

4.2.1. If yes, Specify hours_____

5. Are you currently using any eye care protection when you are exposed to the sun or dust?

Yes	No

Section E: Eye Test Results

1. Results for Schirmer test

Test results will be measured in mm after 5 minutes

Right eye results in mm	Left eye result in mm

2. Results for TFBUT

Tests will be measured in seconds

Right eye in sec	Left eye in sec

Annexure B (Irhumbulo Lemininingwane)
Imibuzo

Data collection tool

Participant Unique Number:_____

Isigaba A: Socio-Demographic Characteristics

1 Iminyaga _____

2 Ubulili Indoda [--] Umfazi [--]

3 Izinga lomfundo

No Schooling	
Primary education	
Secondary education	
Tertiary education	

4 Isimo somtjhato

Single/never married	
Married/co-habiting	
Divorced/separated	
Widowed	

5 Isimo somsebenzi

Working	
Not working	

Section B: Eye conditions

1 Ukhe wahlinzwa amehlo?

Yebo	Qha

2 Ukhe wa hlolisisa amehlo awomileko?

Yebo	Qha

3 Nangabe Iye, usebenzisa Imitjhoga.

4 Kakangaki uhlangobeza nokulandelako?

	Azanke	Ngenkhathi	Kanengi

		ezithileko	
Ukubaba			
Ukuluma			
Ukuoma			
Ukutjhisa			
Ukulila			

5 Ukhe watholakala une Glaucoma?

6 Nangabe iye, usebenzisa imitjhoga ye Glaucoma?

7 Ingabe usebenzisa amabhlere wamehlo wamehlo nofana ama contact lenses?

8 Nangabe Iye impendulweni yeskhomba, bhala imitjhoga oyisebenzisayo

9 Ingabe usebenzisa imotjhoga efana na Antidepresent and anxiety?

Isiqaba C: Izimo ezinye zamagulo

1 Ingabe unesifo esingapheligo?

Yebo	Qha

2 Ngabe Iye. <u>Yisimo siphi tjengisa X ebhokisini</u>

Connective tissue diseases,	
Isifo se sugela	
Systemic hypertension	
Isifo samathambo	
Sjögren syndrome	
Ukutjhota Vitamin A	
Ukugula kwamehlo kofanano blephritis, chronic conjunctivitis, meibomitis, and pengueculapterygium	
Laser vision correction or cataract removal	

3 Usebebzisa imitjhoga ya khona

Yebo	Qha

Yebo	Qha

Yebo	Qha

4 UkuzithwalaMenophosi

5 Ukhe watholakala unesifo se auto immune

Yebo	Qha

ISIGABAD: Umsebenzi

1 ingaba usebenzela endlini

Yebo	Qha

1.1 Nangabe Iye, isilinganiso sama iri ngelanga _____

1.2 Usebenza ama iri amangaki ku, khomphyutha nofana kumaliledini? _____

2 Usebenzela endaweni eno mtjhini we moya?

Yebo	Qha

3 Usebenzisa ababhlere ukuze usebenze

Yebo	Qha

4 Usebenzela ngaphandle

Yebo	Qha

4.1 Nangabe iye, amairi amangaki ngelanga _____

4.2 Usebenzela endaweni enomoya, ilanga nethuli

Yebo	Qha

4.2.1 Ngabe iye amairi emangaki_____

5 Ingabe usebenzisa limvikeli zamehlo nawuqalene nelanga

Yebo	Qha

Isigaba E: imiphumela yokuhlolwa kwamehlo

1. Imiphumelela yokuhlolwa yeSchirmer,

Imiphumelela yokuhlolwa izokumedwa ngama mm ngemva kwemizuzu emihlano

Ilihlo langesindlenin gama mm	Ilihlo langesingeleni ngama mm

2. Imiphumelela ye TFBUT

Imiphumelela yokuhlolwa izokumedwa ngama mm ngemva kwemizuzu emihlano

Ilihlo langesindlenin nge mizozo	Ilihlo langesingeleni ngemizozo

APPENDIX C: Letter seeking permission from Mpumalanga Department of Health

P.O.BOX 4986
Polokwane
0700

The Head of Department
Private Bag X11285,
Mbombela, 1200

Sir/ Madam

REQUEST FOR PERMISSION TO CONDUCT A RESEARCH STUDY

I am a student at the University of Limpopo, currently registered for Masters in Public Health. I hereby request permission to conduct a research study. The title of the research is: The prevalence and the determinants of dry eyes amongst people living in Kwa Mhlanga Township in Mpumalanga. My approved research proposals together with ethical clearance areattached.

Regards:

_____ _____

MefaneTK Date

APPENDIX D: Letter seeking permission from in Kangala District

P.O.BOX 4986
Polokwane
0700

Private Bag X4041,
EMPUMALANGA,
0458
Sir/ Madam

REQUEST FOR PERMISSION TO CONDUCT A RESEARCH STUDY

I am a student at the University of Limpopo, currently registered for Masters in Public Health. I hereby request permission to conduct a research study in villages within Kwa-Mhlanga Township area.
The title of the research is: The prevalence and the determinants of dry eyes amongst people living in Kwa Mhlanga Township in Mpumalanga. My approved research proposals together with ethical clearance areattached.

Regards:

_____ _____

Mefane TK Date

APPENDIX E: Letter seeking permission from Fokus Optometrist

P.O.BOX 4986
Polokwane
0700

Private Bag X4041
EMPUMALANGA
0458

Sir/ Madam

REQUEST FOR PERMISSION TO CONDUCT A RESEARCH STUDY

I am a student at the University of Limpopo, currently registered for Masters in Public Health. I hereby request permission to conduct a research study in villages within Kwa Mhlanga area.

The tittle of the research is: The prevalence and the determinants of dry eyes amongst people living in Kwa Mhlanga Mpumalanga province. My approved research proposal together with ethical clearance is attached.

Regards:

_____ _____

Mefane TK Date

APPENDIX F: CONSENT LETTER FOR RESPONDENTS – ENGLISH

TOPIC: The prevalence and the determinants of dry eyes amongst people living in Kwamhlanga Township

DECLARATION OF CONSENT (RESPONDENTS)

I, the respondents, hereby give permission to voluntarily participate in this research study with the following understanding:

- The researcher conducting the study is a student from University of Limpopo (Turfloop Campus).
- The research forms part of the requirements for student's Master's degree of Public Health
- Information will be collected by means of self-administered questionnaire

My rights as the participant

I cannot be forced to participate in this study.

I have the right to withdraw from the study any time should I wish to.

I have the right to decline to answer any question(s) I am not comfortable with.

I will remain anonymous and my name and identity will be kept from public knowledge.

Any information I reveal during the process of this study shall remain confidential, shall only be used for the purposes of this research and for publication in student's dissertation, and relevant or appropriate publications.

I grant permission for any information I reveal during the interview process, with the understanding that data collected will remain in possession of the researcher, and her supervisor.

I……(Respondents), agree to participate in this study.

SIGNATURES

_____ _____

Participant Date

APPENDIX G: CONSENT LETTER FOR RESPONDENTS – NDEBELE

ISIHLOGO: UkwandanokwenziwakwamehloawomilekoebantwiniabahlalaelokitjiniyawaMhlanga

UKWEHLISA KWEMVUMO

Mina
umphendulinginikezaumvumoyokuhlanganyelangokuthandakwamikukhubhululolokukhubhululangokuzwinsisaokulandelelako:

- UmrhubhululiobuenzairhubhululoungumfundaokuUniversithi ye Limpopo.
- Irhumbululolakhainqenyeyeendingoyeziquzabafundibezepiloyomphakathi.
- Imniningwaneizokubuthelelwangehlelolemibuzoozisebenzelako.

AMALUNGELO WAMI NJE NGOMHLANYELI

-Angezengakatelelwaukuhlanganelaerhubhululwenileli.
-Nginelungelolokuzitsomulaerhubhulwenililingeskhathiengifunangaso.
-Nginelungelolokwalaukuphendulaimibuzoengizwaingangihlalelikuhle.
-Ngizohlalangingaziwa, ibizonobunikazibamiongezebukhitjhelwaemphakathini.
-
Nomangiyiphiimniningwaneengiyivezahlangananrhumbhuloizokuhlalaiyifihlo,izikusetjensiswakwaphelangehlosoyerhumbhululobegodu I qaliswekabafundibomphakathi.

Nginikezaimvumonanomangiyiphiiminingwaneengiyivezangeskhathiserhumbhululongokuzwisanabonyanaizokuhlalaphakathikomrhumbhulonomphakathiwakhe,

Mina…….
(umphenduli), Ngiyavumaukuhlakanyelakurhumbhuloleli.

UKUTLIKITLA

_____ _____

Ahlanganyelani

APPENDIX H: INSTRUCTION TO PARTICIPANTS – ENGLISH

Dear Respondent

I am a Masters of Public Health (MPH) at the University of Limpopo Turfloop Campus. You are kindly invited to participate in the research study which forms part of my MPH degree programme. As part of the study, I am expected to collect data from identified respondents and that includes you. The study seeks examine how prevalent is dry eye disease and what is the determinant of dry eye disease. The expected benefit of this research is to develop a better understanding and identification of causes and risk factors that have been linked with DED in these areas. An understanding of epidemiological differences in these areas will also facilitate our understanding of specific pathologies and the choice of therapeutic modality.

The questionnaire will be used to collect date which will take approximately 30-45 minutes. Please read the directions carefully before proceeding. You may choose to withdraw from the study at any time. You are also requested to be honest in answering the questions. Should you consent to participate in the study, kindly read and sign the informed consent form provided to you.

Thank you in anticipation of your participation.

_____ _____

Mefane TK Date

Masters of MPH Candidate

University of Limpopo- Turfloop Campus

APPENDIX I: INSTRUCTION TO PARTICIPANTS – NDEBELE

LotjhaMphenduli

NgigumfundiophakamilekokomphakathieYunivesithi ye Limpopo (Turfloop Campus). UmenywaMayelananokuhlanganyelakurhubhululolehlelolamielifakahlanganaizuquze MPH.
Njengomhlanganyeliwerhumbhulongilindelekebonyanangifunyaneimininingwaneevel aebantwiniozobakhombaokofakaphakathinawe.
Irhumbhululoifunautjhegebonyanaisifosokomakwamehlosandekanganganibegoduyini unobangela. Imiphumelaelindelwekurhumbhulokukwandisisakanyenebangela, nobungoziezifakahlanganaiindawoze DED.
Ukuzwisisakwamaguloahlukenekokulendawoizokwenzakubelulaukuzwisisakwe pathologies ethilekokanyenokuthethwaihlathululolokulapha.

Imbuzoizokusetjensizwaukubuthelelaimininingwaneezikokuthathaimizuzuematjhumia mathathonemizozoemihlanu.
Sibawaumfundisiseiikombangaphambikokubonauragelephambili.
Ungakhethaukuzitsomulakurhumbhululongeskgathiofunangaso.
Sibawaubeneqinisonawuphendulaimibizo.
Nawuvumaukuhlanganyelakurhumbhululosibawaufundebewutlikitleiforomolemvumoo nikelwalona,

Siyabonga

_____ _____

Mefane TK

University ye Limpopo eTurfloop

APPENDIX J: Approval from Turfloop Research Ethics Committee (TREC)

University of Limpopo
Department of Research Administration and Development
Private Bag X1106, Sovenga, 0727, South Africa
Tel: (015) 268 3935, Fax: (015) 268 2306, Email: anastasia.ngobe@ul.ac.za

TURFLOOP RESEARCH ETHICS COMMITTEE

ETHICS CLEARANCE CERTIFICATE

MEETING: 12 August 2020

PROJECT NUMBER: TREC/175/2020: PG

PROJECT:

Title:	The Prevalence and Determinants of Dry Eye Disease Amongst People Living in Kwa-Mhlanga
Researcher:	TK Mefane
Supervisor:	Dr E Maimela
Co-Supervisor/s:	Mr J Ramaja Prof S Mathebula
School:	Health Care Sciences
Degree:	Master of Public Health

PROF P MASOKO
CHAIRPERSON: TURFLOOP RESEARCH ETHICS COMMITTEE
The Turfloop Research Ethics Committee (TREC) is registered with the National Health Research Ethics Council, Registration Number: **REC-0310111-031**

Note:
i) **This Ethics Clearance Certificate will be valid for one (1) year, as from the abovementioned date. Application for annual renewal (or annual review) need to be received by TREC one month before lapse of this period.**
ii) **Should any departure be contemplated from the research procedure as approved, the researcher(s) must re-submit the protocol to the committee, together with the Application for Amendment form.**
iii) **PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES.**

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APPENDIX K: Approval from Mpumalanga Department of Health

health
MPUMALANGA PROVINCE
REPUBLIC OF SOUTH AFRICA

Indwe Building, Government Boulevard, Riverside Park, Ext. 2, Mbombela, 1200, Mpumalanga Province
Private Bag X11285, Mbombela, 1200, Mpumalanga Province
Tel I: +27 (13) 766 3429, Fax: +27 (13) 766 3458

Litiko Letemphilo | Departement van Gesondheid | UmNyango WezeMaphilo

Enq: 013 766 3766/3511
Ref: MP_202009_002

Provincial Research Approval Letter

Mrs Tlou Kate Mefane
P.O BOX 2119
BRONKHORSTSPRUIT 1020

TITLE: **APPLICATION FOR RESEARCH APPROVAL: THE PREVALENCE AND DETERMINANTS OF DRY EYE DISEASE AMONGST PEOPLE LIVING IN KWA-MHLANGA**

Dear Mrs Mefane

The Provincial Department of Health Research Committee has approved your research proposal in the latest format you sent.

- Approval Reference Number: MP_202009_002
- Data Collection Period: 01/10/2020 to 20/08/2021.
- Approved Data Collection Facilities: KwaMhlanga Clinic & KwaMhlanga Hospital

Kindly ensure that conditions mentioned below are adhered to, and that the study is conducted with minimal disruption and impact on our staff, and also ensure that you provide us with a soft or hard copy of the report once your research project has been completed.

Conditions:
- *Researchers not allowed to make copies or take pictures of medical records.*

Kind regards

DR C NELSON
MPUMALANGA PHRC CHAIRPERSON
DATE: 21 October 2020

MPUMALANGA
THE PLACE OF THE RISING SUN

APPENDIX L: Evidence of language editing

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0700 Tel: 072 190 2999 • Fax: 0864154022

Date: 08 June 2021

To Whom it May Concern

I hereby confirm that I have proof-read the document entitled: "The prevalence and determinants of dry eye disease amongst people living in Kwa-mhlanga" authored by Mefane TK with student number 200014080. The document has been edited and proofread for grammar, spelling, punctuation, overall style and logical flow. Considering the suggested changes that the author may or may not accept, at his discretion, each of us has our own unique voice as far as both spoken and written language is concerned. In my role as proof-reader I try not to let my own "written voice" overshadow the voice of the author, while at the same time attempting to ensure a readable document.

Please refer any queries to me.

Rapetsoa DB