# PREVALENCE OF UNMET NEED AND FUNCTIONAL STATUS OF RURAL SOUTH INDIAN ADULTS WITH PRESBYOPIA

# - A CROSS SECTIONAL STUDY



# DISSERTATION SUBMITTED TOWARDS FULFILLMENT OF THE RULES AND REGULATIONS FOR THE M.S BRANCH III OPHTHALMOLOGY

DEGREE EXAMINATION OF THE TAMIL NADU DR.M.G.R. MEDICAL UNIVERSITY TO BE HELD IN MAY, 2020

**REGISTRATION NUMBER:** 221713302

# PREVALENCE OF UNMET NEED AND FUNCTIONAL STATUS OF RURAL SOUTH INDIAN ADULTS WITH PRESBYOPIA

# - A CROSS SECTIONAL STUDY



DR DIVYA GIRIDHAR

CHRISTIAN MEDICAL COLLEGE, VELLORE

# **BONAFIDE CERTIFICATE**

This is to certify that this dissertation "Prevalence of unmet need and functional status of rural South Indian adults with presbyopia – a cross sectional study" done towards fulfilment of the requirements of the Tamil Nadu Dr MGR Medical University, Chennai for the MS Branch III (Ophthalmology) examination to be conducted in May 2020, is a bona-fide work of Dr. Divya Giridhar, post graduate student in the Department of Ophthalmology, Christian Medical College, Vellore.

Dr Padma Paul Dr Anika Amritanand

DO, MS, DNB, MPH MS, MSc (Community Health)

Professor Associate Professor

Department Of Ophthalmology Department Of Ophthalmology

Christian Medical College Christian Medical College

Vellore 632001 Vellore 632001

# **BONAFIDE CERTIFICATE**

This is to certify that this dissertation "Prevalence of unmet need and functional status of rural South Indian adults with presbyopia – a cross sectional study" done towards fulfilment of the requirements of the Tamil Nadu Dr MGR Medical University, Chennai for the MS Branch III (Ophthalmology) examination to be conducted in May 2020, is a bona-fide work of Dr.Divya Giridhar, post graduate student in the Department of Ophthalmology, Christian Medical College, Vellore.

Dr. Sanita Korah, DO, MS, DNB

Professor, Head of the Department,

Department of Ophthalmology,

Christian Medical College,

Vellore - 632001.

**BONAFIDE CERTIFICATE** 

This is to certify that this dissertation "Prevalence of unmet need and functional

status of rural South Indian adults with presbyopia – a cross sectional study"

done towards fulfilment of the requirements of the Tamil Nadu Dr MGR Medical

University, Chennai for the MS Branch III (Ophthalmology) examination to be

conducted in May 2020, is a bona-fide work of Dr.Divya Giridhar, post graduate

student in the Department of Ophthalmology, Christian Medical College, Vellore.

Dr. Anna B. Pulimood, MD,Phd

Principal,

Christian Medical College,

Vellore – 632001.

5

**DECLARATION** 

I hereby declare that this dissertation entitled 'Prevalence of unmet need and

functional status of rural South Indian adults with presbyopia – a cross sectional

study' done towards fulfilment of the requirements of the Tamil Nadu Dr MGR

Medical University, Chennai for MS Branch III Ophthalmology examination to be

conducted in May 2020, comprises my original research work, and information taken

from secondary sources has received due acknowledgment and citation.

Dr Divya Giridhar

Postgraduate Student (MS Ophthalmology)

Registration Number: 221713302

Department of Ophthalmology

Christian Medical College

Vellore 632001

6

# URKUND ANALYSIS REPORT



# **Urkund Analysis Result**

Analysed Document: THESIS FINAL\_DIVYA\_2 - Copy (2) for plagarism.docx (D58341998)

**Submitted:** 11/6/2019 6:30:00 AM **Submitted By:** divg1212@gmail.com

Significance: 13 %

### Sources included in the report:

latest thesis .25.12.2017.docx (D34204033)

https://www.researchgate.net/publication/7060268\_A\_Population-

Based\_Assessment\_of\_Presbyopia\_in\_the\_State\_of\_Andhra\_Pradesh\_South\_India\_The\_Andhra\_

Pradesh\_Eye\_Disease\_Study

https://www.sciencedirect.com/science/article/pii/S2214109X17302930

https://www.researchgate.net/figure/Differences-in-the-proportions-of-

respondents\_fig2\_282050659

https://entokey.com/overview-of-presbyopia-and-its-medical-management/

https://iovs.arvojournals.org/article.aspx?articleid=2187372

https://www.touchophthalmology.com/presbyopia-related-functional-impairment-and-

spectacle-use-in-rural-kenya/

https://www.researchgate.net/

publication/7130163\_Impact\_of\_Presbyopia\_on\_Quality\_of\_Life\_in\_a\_Rural\_African\_Setting

https://iovs.arvojournals.org/data/journals/iovs/932938/z7g00606002324.pdf

https://iovs.arvojournals.org/article.aspx?articleid=2125147

### Instances where selected sources appear:

36

# **ANTI PLAGIARISM CERTIFICATE**

This is to certify that the dissertation work titled 'Prevalence of unmet need and functional status of rural South Indian adults with presbyopia – a cross sectional study' has been submitted by the candidate Dr. Divya Giridhar with Registration number: 221713302 for the award of degree of MS Ophthalmology Branch III.

I have personally verified the Urkund.com website for the purpose of plagiarism check. I have found that the uploaded thesis file from introduction to conclusion shows 13% of plagiarism in the dissertation.

Dr. Sanita Korah, DO, MS, DNB

Professor, Head of the Department,

Department of Ophthalmology,

Christian Medical College,

Vellore - 632001.

# **DEDICATED TO**

# Late Mr Yovan

I thank Mr Yovan for constantly motivating me from the start of the study.

I thank him for providing timely and valuable suggestions on how to improve our study methods.

Also lastly, I am so grateful to him for agreeing to administer the questionnaire, which was a key part of our study.

I will always remember him for his positive outlook to life.

# **ACKNOWLEDGEMENT**

Firstly I thank God for giving me the chance and the capability to do my thesis.

I thank my guide, Dr. Padma Paul and co-guide Dr Anika Amritanand for giving me the opportunity to conduct this study. I thank them for their timely suggestions, constant support and motivation throughout my study.

I thank Dr Thomas Kuriakose for his valuable suggestions. I thank Dr. Vinod Abraham for granting me permission to conduct my study.

I thank Mr Prem for all the help he has provided throughout my study. I also thank Mr. Xavier for his help and support.

I thank Mrs Sarala, Mr. Senthil Kumar and Mr Arul to help me organise the study clinic and encourage patients to attend the same. I thank Mr Suresh for arranging timely transport to the study clinic.

I extend my sincere thanks to Mr Yovan, Mr Deenadayalan, Mr Pashupathy, Mr Hitler, Mr Ravi, and Mrs Shirley for their support and help.

I thank Mrs Reka and Miss Dona for helping me with the analysis.

I want to thank all the patients who participated in the study, because of whom this research was possible

I thank my colleageus, Dr Swetha, Dr. Reshmi, Dr. Sharmila S, Dr Nithin, Dr. Susan, Dr Aneena, Dr Thuhin for their support.

I finally want to thank my parents and sister for their support and motivation.

# **CONTENTS**

INTRODUCTION	12
AIMS	15
OBJECTIVES	16
REVIEW OF LITERATURE	17
MATERIALS AND METHODS	36
RESULTS	48
DISCUSSION	76
LIMITATIONS	85
CONCLUSION	87
REFERENCES	89
APPENDIX	93
i) IRB APPROVAL LETTER	94
ii) PATIENT INFORMATION SHEET	98
iii) INFORMED CONSENT	105
iv) DATA COLLECTION SHEET	111
y) DATA	119

# **INTRODUCTION**

Visual impairment is a global visual challenge. Globally, among the 7.33 billion people alive, 36 million are blind, 216.6 million (80%) had moderate to severe visual impairment. The prevalence of presbyopia is 35.6% for persons 35 years and older(1,2). In India, The NPCB-WHO survey (1986-1989) had shown that there are over 12 million people who were blind, and 80% of them were diagnosed with cataract. Refractive error, trachoma, glaucoma, central corneal blindness were the other causes of blindness. India was one of the first countries in the world to initiate a public funded program aimed towards the control of blindness as a national priority health program (3). With the launch of Vision 2020: The Right to Sight Initiative, the focus has shifted to other causes of avoidable blindness other than cataract alone.

Refractive error is considered globally as one of the important causes of treatable visual impairment. Various population based studies performed in Southern India have shown that uncorrected refractive error is the leading cause of visual impairment followed by cataract.(4) The treatment of refractive error is by prescribing corrective spectacles, which makes it easier to treat compared to other ocular diseases.

Presbyopia is another common cause of visual impairment, mainly among persons above 30 years of age. Presbyopia is a condition that mainly affects the near vision of the individual due to age related loss of accommodation. It is also one of the common reasons for spectacle use among adults. Like refractive error, presbyopia can also be

easily corrected by a simple eye test and economical spectacle correction and therefore should not remain undetected and untreated.

In low income regions and rural areas, presbyopia has been found to be a major cause for non-blinding visual impairment. Yet, presbyopia is not considered as a cause of visual impairment in the Vision 2020 global initiative, although refractive error is included. Presbyopia is also not included in the WHO report along with refractive errors(5) Globally there are very few major studies to assess the impact of presbyopia, as the cause for visual impairment and the possible socio economic impact

Near vision not only helps us in reading and writing but it is essential in helping an individual to perform any task related to near work. In rural areas, majority of the individuals are illiterate and thus not being able to perform daily household activities that require near vision can impact their quality of life.

To quantify the burden of presbyopia in a certain population, it is important to estimate the prevalence and unmet need of presbyopia. However, there is also limited information regarding functional status in an Indian presbyopic population. The purpose of our study is to try and fill this gap especially in our region.

# **AIM OF THE STUDY**

To determine the prevalence of unmet need and functional status of presbyopia in population 30 years and above in rural South India.

# **OBJECTIVES**

- 1. To determine the overall prevalence of uncorrected presbyopia and spectacle coverage in this population.
- 2. To determine the distribution of ocular morbidity in the study population.
- 3. To determine functional status of patients with presbyopia, determine the levels of near vision at which difficulty sets in and identify the barriers associated with not using spectacles.

# **REVIEW OF LITERATURE**

Normal vision depends upon the ability of the ocular lens to change shape, ensuring that light is focused on the most sensitive part of the retina. Anyone living beyond middle age is inevitably affected by presbyopia, an inability to focus on near objects, due to the loss of flexibility of the ocular lens.

Most of the people with uncorrected visual impairment live in low- and middle-income countries. (6)

According to the WHO estimates, 2.2 billion individuals have visual impairment or blindness.(5). The global target for the global action plan is to reduce the prevalence of visual impairment by 25% ( of the prevalence in 2010) by 2019 as compared to the prevalence established in 2010(7). Globally, cataract and uncorrected refractive error are the main causes of blindness visual impairment respectively. The revised estimates of those with vision impairment, which included uncorrected refractive error, were published in 2004, 2010 and 2013(8). Unfortunately, impairment of near vision was not included due to insufficient data on the prevalence of the condition.

It has been estimated that 108 million people worldwide have impaired distance vision(9), while nearly five times as many (517 million people) have impaired near vision., which can be treated with the use of spectacles.(9)

Considering near vision, rates of uncorrected near vision impairment are reported to be more than 80% in western and central sub-Saharan Africa, while in high-income regions of North America, Western Europe, and of Asia-Pacific rates are lower than 10% .(9)

Near vision impairment affects the quality of life as much as impairment of distance vision, regardless of the setting, socio-demographic or lifestyle of participants and according to the recent WHO statistics, uncorrected presbyopia is considered as the most common cause of visual impairment.(5)

# **PRESBYOPIA**

The term 'presbyopia' refers to the gradual loss of accommodation by the crystalline lens with advancing age. It is associated with difficulty with near vision and patients typically become symptomatic when approaching middle age(10). They may report blurry vision when doing near work, headaches, asthenopia, squinting and eye strain. The changes in accommodation maybe related to changes in the ciliary muscles, lens, capsule of the lens, and/or changes in the vitreous, but are age related. It is an important cause of visual impairment among adults above 40 years of age. Identification of presbyopia is important because it is an easily correctable cause of vision loss in an aging individual with no other ocular morbidity, with many affordable nonsurgical and surgical management options. For previously emmetropic individuals the experience of developing a new dependency on corrective lenses may be distressing. Health care professionals should reassure these patients and explain to them that it is a normal physiological change and refer them to an ophthalmologist for further treatment and evaluation. In developing nations, presbyopia remains widely untreated due to limits in access to eye care (11).

# **DEFINITIONS**

The terminology with reference to presbyopia has been described as follows.

**Presbyopia** (functional presbyopia) is defined as binocular near vision < N8 at 40 cm with habitually worn distance refractive correction, with improvement of near vision by at least one line in a near vision chart with plus lenses.(12–14)

- Unmet Presbyopic Need (UPN) (14)— Number unable to see N8 binocularly, with near vision spectacle used.
- Met Presbyopic Need (MPN) (14) It is the measure of the distribution of spectacles for near vision in order to correct those with presbyopia to N8 or better binocularly.
- **Presbyopic Correction Coverage** (PCC) (14) Measure of presbyopia requiring correction with spectacles in order to see N8 or better binocularly.
- WHO classification for **blindness and visual impairment** (5)
- Mild visual impairment presenting visual acuity worse than 6/12 in the better eye.
- Moderate visual impairment presenting visual acuity worse than 6/18 in the better eye.
- Severe visual impairment presenting visual acuity worse than 6/60 in the better eye.

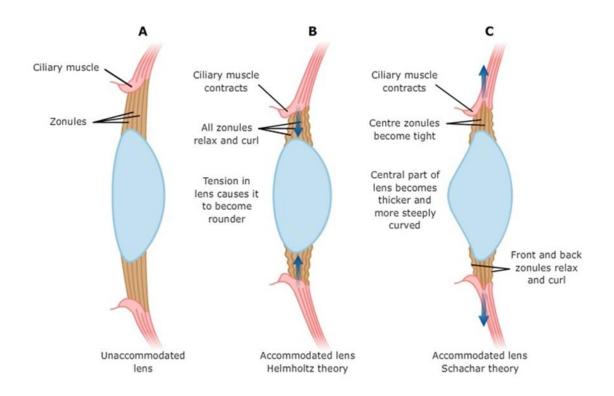
- Blindness – presenting visual acuity worse than 3/60 in the better eye.

# PHYSIOLOGY OF ACCOMMODATION

The mechanism of accommodation has been a source of scientific inquiry for more than half a century. In 1855, a German physicist by the name of Hermann von Helmholtz proposed what has become the predominant paradigm used to explain the relationship between accommodation and the ciliary muscle.(15) According to von Helmholtz, whenever a subject is focused on a distant object, the relaxed ciliary muscle keeps the zonular fibers at a resting tension because the internal diameter of the ciliary muscle is maximized. This places tension on the lens equator, which flattens the lens and diminishes its dioptric power. During accommodation, the ciliary muscle, which is a sphincter muscle, contracts so that the internal diameter decreases, which releases tension on the zonules. As the zonules relax, the lens capsule constricts, leading to a decrease in the equatorial lens diameter and an increase in the convexity of the anterior and posterior lens surfaces. The end result is a rounder lens that increases the eye's dioptric power so that one can focus on near objects (ie, accommodate) (16)

Another theory was put forward by Danish ophthalmologist named Marius Tscherning explaining the theory of presbyopia.(15) In 1895, he published his theory that ciliary

muscle contraction increases the tension in the zonules, which in turn pushes the cortex around the nucleus to reshape the lens without modifying its thickness. More recent adaptations of Tscherning's theory have been proposed by Ronald Schachar. Schachar has postulated that ciliary muscle contraction during accommodation preferentially increases, rather than decreases, zonular tension at the equator of the lens. The lens curvature thus increases as the equatorial lens is pulled toward the sclera.



# **EPIDEMIOLOGY**

### **Refractive Error**

Globally, almost 95 million people, beyond 50 years of age are visually impaired due to uncorrected refractive errors - the prevalence was between 2% and 5% in most regions of the world (which included Europe, Other Asia and Islands (OAI); Sub-Saharan Africa, Latin America and the Caribbean ), nearly 10% in China and 20% in India and in SEAR-D .(17)

Resnikoff et al concluded that the global prevalence of uncorrected refractive error was 0.96% and 1.1 % among the age groups of 5-15 years and 16-49 years respectively(8). This was the highest prevalence recorded in urban areas in South East Asia and in China.

In India, after the Vision 2020 global initiative, various initiatives have been made to focus on other causes of avoidable blindness other than cataract. The Rapid Assessment of Avoidable Blindness concluded that, among those who were visually impaired, cataract was the commonest cause (58.1%), followed by uncorrected refractive errors (32.9%)(3)

The Rapid Assessment of Visual Impairment which was conducted in East Delhi found that uncorrected refractive error was the most common cause of visual

impairment (53.4%) (18)Similar studies were conducted in South India, where uncorrected refractive errors were the leading cause of visual impairment(4)

Sheela devi et al(19) conducted a recent systematic review in India, among individuals above 30 years of age ,which included fifteen studies from south India, one from central India and Western India and one study that covered fifteen states across India. It was estimated that, 10.2% of the adults were diagnosed with uncorrected refractive error.

# Presbyopia

Presbyopia eventually sets in as age advances, in all individuals, with the onset starting typically around 38 years of age and reaching a peak incidence around 42 to 44 years of age(20). Nearly 100% will become symptomatic by the time they are 52 years old .(20)

Despite the universal development of presbyopia, to estimate the incidence and prevalence of this condition is quite challenging. This can be because of various reasons. Firstly, the assessment of presbyopia is very difficult, since it is age related and has a gradual onset. Secondly, not all individuals with presbyopia will present to an ophthalmologist / clinic with difficulty. They may be asymptomatic initially or will try to manage with this difficulty in the initial stages. This holds true in developing nations, where 94 % of the world's burden of uncorrected vision impairment due to presbyopia (11).

# **Prevalence of Presbyopia**

Globally, due to an increase in life expectancy, the contribution of older persons in the total population is increasing virtually everywhere . This adds to the presbyopic age group. The United Nations estimates that in 2015, there were 901 million people aged 60 years or older. This constituted a 48% increase since the year 2000. By 2050, the global population of older adults is projected to double to nearly 2.1 billion (21)

According to the survey conducted by Holden and colleagues, there were approximately 1.04 billion people with presbyopia in 2005, more than half of these patients either did not have glasses or had inadequate refractive correction, and 410 million had functional impairment when trying to perform near tasks(11)

Globally, in a recent systematic review, the prevalence of functional presbyopia was 35.6% (95% Confidence Interval [CI] 18.9–54.9) for people aged 35 years and older, and 40.3% (95% CI 22.0–60.4) for people aged 50 years and older. (22)

In developed countries like the United States, very few studies on presbyopia have been conducted. The functional near vision impairment was 12.6% among a population above 50 years of age in the United States.(23)

Lu et al conducted a study in Northern China among individuals above 40 years of age, and inferred that the prevalence of functional presbyopia was 67.3%, which was more common among individuals between 60-69 years of age(13)

In a study conducted in rural Tanzania by Patel et al among individuals 40 years of age and older, the prevalence of presbyopia was found to be 62% and majority of the presbyopes (94%) did not use near vision spectacles.(12)

Sherwin et al conducted a study among subjects 50 years and older in a rural Kenyan population, and found the overall prevalence of functional presbyopia to be 85.4%, where the unmet need was 80 %, met need was 5.4% .(14)

The Andhra Pradesh Eye Disease Study (APEDS) which was conducted among 10,000 individuals, was a population based cross sectional study and reported on the various causes, risk factors and prevalence of visual impairment. As a part of the initial study, APEDS also gathered information about the near and distant vision of individuals who were included in the study. This was one of the first studies conducted in India that explored the prevalence of presbyopia among individuals above 30 years of age.

According to Nirmalan et al, the prevalence of presbyopia was 55.3%, amongst individuals above 30 years in the state of Andhra Pradesh in South India. It was also seen that the difficulty in near vision activities were more among the presbyopes not using spectacles compared to those using spectacles(24)

A population based study of subjects 40years and older was also conducted amongst the weaving communities in the state of Andhra Pradesh and concluded that the prevalence of presbyopia was 61.8%, that of functional presbyopia was 35.1%(25). In this study functional presbyopia was presenting vision less than N8, improving to N8 or better with addition of plus lenses.

In India, the rapid assessment of visual impairment survey in New Delhi conducted among those above 40 years of age found that presbyopia prevalence was 34.2% and among the presbyopes 34.1% were using spectacles(18)

Marmamula et al, as part of the Rapid Assessment of Refractive Errors survey in South India reported that the overall prevalence of presbyopia was 63.2%(26)

# MET AND UNMET NEED OF PRESBYOPIA

In a study conducted in Timor-Leste among individuals aged 40 years and above, the met need for presbyopia was 11.5% and the unmet need was 32.3%. The spectacle coverage was low and was common among those who were illiterate and farmers (27). In a Kenyan population, among presbyopic individuals more than 30 years, the unmet need was 80.0%, met need was 5.4% (14).

### FACTORS ASSOCIATED WITH PRESBYOPIA

- Age. As mentioned previously, presbyopia is related to the age related changes in the lens and zonules. Age, has therefore had strongest association with Presbyopia.(11) On an average, the accommodative amplitude declines -1.0 diopter (D) for every 4 years, falling to  $6.0 D \pm 2.0 D$  around the age of 40 years. Loss occurs at a faster rate of -1.5 D for every 4 years between the ages of 40 to 48 years, and then slows down to an average of -0.5 D decline every 4 years once one reaches 48 years old(10)
- *Gender* Females are said to develop presbyopia at an earlier age compared to males(28). The reason for this disparity is not clear. Females require more plus corrective lens to correct the presbyopia (29,30). It has been said that this can be due to shorter arm lengths in women compared to men, rather than true anatomic

differences in the eye (31). According to Daza de Valdes there can be two reasons for this: women perform "more delicate work" and naturally have "weaker vision."

Another reason is hormonal factors which contribute to the earlier onset (24)

# • Geographical factors

Onset of presbyopia varies among large segments of the world's population. For instance, according to Kajiura, the present day average age of onset of presbyopia is 47 years of age, which was explained by the greatly improved hygienic and economic conditions of the Japanese since World War II; whereas Ishihara found the average age to be 43 years in 1919 (32)

Another factor is the exposure to solar radiation – those who live closer to the equator develop presbyopia at an earlier age. Thus those who live in the tropics are said to develop presbyopia earlier than Mid Europeans and Scandinavians (32,33). Also, in regions like Alaska, where the mean average temperature is 42 deg F, the onset is much later (44 years) compared to Puerto Rico, which is closer to the equator; onset is earlier (39-40 years). This is due to exposure to solar radiation that reaches the lens, of which 310 – 400 nm ultraviolet radiation is specifically known to accelerate aging.

• *Ethnicity*- Prevalence is more among blacks compared to whites and Mexican Americans. The prevalence in the west in 13.6%, less compared to the Indian

studies(23). In an Asian population, Indians and Malays were associated with higher odds of presbyopia compared to Chinese individuals (34).

- *Occupation* Individuals whose daily activities include near work, may complain of asthenopic symptoms earlier due to accommodative fatigue as they approach middle age (12)
- *Diabetes Mellitus* Those who are diabetic are said to have an earlier onset of presbyopia, probably 3 to 5 years earlier. This has not been related much to the duration of diabetes. This is attributed to the decrease in amplitude of accommodation in these individuals(35)

Refractive errors – Those individuals with myopia and hyperopia are said to have a strong association with presbyopia.(24)

• The onset of presbyopia depends on various other factors such as the ocular refractive condition, the general health of the person, the type of correction (32)

# **SPECTACLE USE**

The treatment of presbyopia and refractive error is by the use of corrective spectacles and thus is very cost effective. Even though the prevalence of presbyopia is high in many population based studies, the spectacle coverage is not adequate.

The percentage of individuals who have presbyopia and are not wearing spectacles varies between regions. The principal barriers to spectacle use among persons with functional presbyopia have been assessed in various studies. Cost has been one of the main reasons, followed by others like lack of need. (11)

In a study in Rural China, among the 538 persons with presbyopia, 60.8% were reported to have spectacles for near vision, majority of whom obtained them from optical shops rather than from eye clinics (74.5% vs 1.14%) (13)

•Similar studies in a Kenyan population concluded that, among 134 participants in the study the presbyopic correction coverage was 6.3%, the main source of spectacles was hospital eye unit (36.7%) and the principal barrier to spectacle use was cost (62.2%)(14)

In a study conducted in Southwest Nigeria, among 440 participants above 40 years of age, the presbyopic correction coverage was 27.3%. Also the main barrier was 'not a priority (38.4%) and 'not aware of the problem' (34.7%) (36).

The challenges and practices of spectacle wearers were studied among a Nigerian population, where 214 individuals above 18 years of age were included. They reported that the reason for not using spectacles was 'cost'(40%) (37)

In South India, in a rural population in Andhra Pradesh, among the 3907 presbyopic individuals above the age of 30 years, only one third of them were using spectacles (30.0%) (24). In a similar study in Telengana state, 6150 individuals above 40 years were included; the spectacle coverage was 53.6% and private eye clinics were the commonest providers(38).

In a similar study among the weaving communities in the state of Andhra Pradesh, it was found that the spectacle correction coverage was 43.2%, and the most common barrier was 'discomfort with spectacle use'(25)

# FUNCTIONAL NEED ASSESMENT AND QUALITY OF LIFE

In a rural setting, majority of the people are illiterate, thus it becomes necessary to assess their difficulty in performing other daily activities.

The near vision related difficulty affects the quality of life, such as difficulty in harvesting sorghum, threading a needle, writing letters in a Tanzanian population(12), difficulty with activities of daily living, functional dependence and social functioning in a Chinese population (13). Even in rural areas and developing countries, with the increased use of mobile phones and computer, the demand for near vision and near vision correction is increasing.

According to Sherwin et al, functional presbyopia was more common among females and younger individuals. Among those with functional presbyopia, 88.3% had difficulty with reading and the task that was associated with greatest vision related difficulty was sewing(14).

According to Lu et al, about 90% of those with presbyopia experienced some level of difficulty with activities of daily living. The vision was significantly worse amongst those with presbyopia compared with those without (p<0.001). Also, those with presbyopia reported requiring help from others due to their vision and sense of decreased accomplishment compared to those persons without presbyopia.(13)

Patel et al also assessed the near vision related difficulty score among the presbyopes above 50 years of age and about 70% of those who had any degree of functional presbyopia had some level of near vision related difficulty. As the degree of functional presbyopia increased, more subjects experience 'high difficulty' in the activities(39).

McDonnell et al, assessed impact of health related quality of life with presbyopia and reported worsening of quality of life among presbyopes compared to emmetropes belonging to the same age group(40).

According to a study in South India among individuals above 40 years of age, the prevalence of presbyopia was found to be 70% (25) Also, 53% of individuals with functional presbyopia experienced difficulty with near tasks. However they have not used any questionnaire based survey to assess the level of functional disability.

It has also been observed that presbyopes reported twice the rates of dependency to carry out daily activities. It was reported that a total of 244 million cases of uncorrected or under corrected presbyopia above the age of 50 years exist which would be associated with a potential productivity loss (0.016% of the global GDP). (41)

# DEVELOPMENT AND ASSESSMENT OF QUESTIONNAIRES

In addition to the traditional methods of treatment of diseases based on signs, symptoms, morbidity and mortality; it is also important to assess the impact of a disease on one's health related quality of life.

Health related quality of life is commonly measured using questionnaires (called 'instruments'), which are efficient tools to gather large amount of data quickly (42). One of the main objectives of an instrument is to determine the attitude of the people and also how the range of attitudes is distributed in the population (43)

# MATERIALS AND METHODS

#### Study Design:

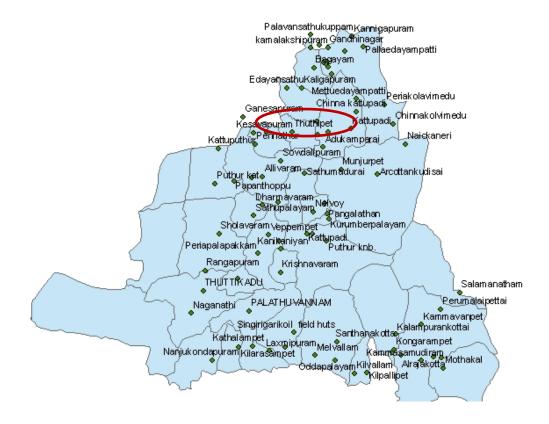
Population based cross sectional Study

#### Setting:

The study was conducted in the Kanayambadi block of Vellore district. It has 82 villages with a population of over 116,214 individuals as per the 2011 census. This is the rural service area of the community health department of our institution. The Community Health Department of our institution provides primary care to rural, urban and tribal communities nearby. The department has established a network of community-based health care throughout the Kaniyambadi block, allocated to it by the government. The Kanayambadi block has three Primary Health Centres each having a Para Medical Ophthalmic Assistant. There is one district hospital located in this which is the Government Vellore Medical College.

#### **Study Population:**

One village was randomly selected for the study. All the individuals 30 years and older were eligible for the study. The list of eligible individuals was obtained from the database of the Community Health and Development (CHAD) program.



### **Study Participants**

All consenting individuals above 30 years of age in the selected village were included in the study. Health Aids (HA), who are grass root level workers, in CHAD hospital were given a list of eligible individuals. They conducted door to door visits to encourage individuals to attend the study clinics which were conducted on predetermined dates at predetermined sites in the respective village.

#### Inclusion criteria:

All consenting individuals above the age of 30 years were eligible to be included in the study.

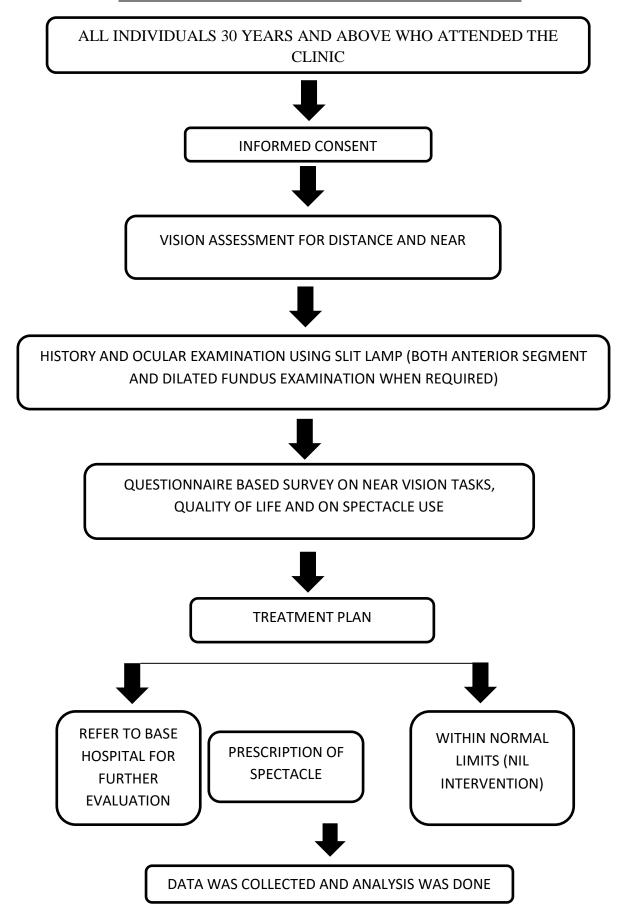
# Period of Study:

June 2018 – June 2019

# Institutional Review Board Clearance:

The study was cleared by the institutional ethics and research committee of the Christian Medical College (CMC), Vellore.( Ref no: 11357 )

#### DIAGRAMMATIC ALGORITHM OF THE STUDY



#### **CLINICAL EXAMINATION**

The individuals who met the eligibility criteria were included in the study. Before the start of examination, a trained health worker obtained a written informed consent from each individual. and filled the demographic details of each person into the proforma which included age, education, occupation and if they had any systemic co-morbidity. This was followed by a comprehensive eye examination, which was done for all the individuals by two optometrists and an ophthalmologist (Principal Investigator) Two trained social workers then administered the questionnaire which included information regarding the type of work individuals are able to perform with/without spectacles and their need for spectacles. The questionnaire that was used for the study has been included in the Appendix.

A comprehensive eye examination included vision assessment, for both near and distance. The distant vision was tested using a self- illuminated three metre LogMar chart with 'E' optotype. Near vision was assessed using Snellen's near vision E chart at 40 cm distance. This was converted to 'M' notation at the time of data entry for better and easier analysis. This distance was measured using a string attached to the top of the chart at one end, the other end of which is placed the subjects forehead and held taut. The vision assessment included unaided vision, pinhole vision, presenting vision (with the spectacle correction they are presently using) and the best corrected visual acuity for both near and distance. This was followed by ocular examination including assessment of pupils, anterior segment, measurement of intraocular

pressures (using Goldmann applanation tonometer) and detailed examination of lens, vitreous and fundus (using a slit lamp- Appasamy AIA-11 2S). An undilated fundus examination was done for all the participants of the study. A detailed dilated fundus examination was done on the slit lamp for all diabetic patients and for those whom best corrected visual acuity did not improve beyond 6/18 using a 78 D or 90 D volk lens when possible.

For those individuals who could not attend the study clinic, door to door visits were conducted. Vision was assessed using Snellen's chart at 6 metres (converted to logMar) with 'E' optotype and near vision using near vision 'E' chart at 40cm distance with adequate light source. This was then converted to M notation of the LOG MAR near vision chart for the purpose of analysis. Ocular examination was done using a hand held slit lamp (Reichert) for the anterior segment, Direct Ophthalmoscope (Welsch - Allyn) for fundus examination and indirect ophthalmoscope (Appasamy) with 20D lens when required.

#### **DEFINITIONS**

For the purpose of our study the various definitions we used are as follows:

• **Presbyopia** (functional presbyopia) is defined as binocular near vision N8 at 40 cm with habitually worn distance refractive correction, with improvement of near vision by at least one line in a near vision chart with plus lenses

#### **FORMULAS**

- Unmet Presbyopic Need (UPN) Number unable to see N8 binocularly, with near vision spectacle used.
  - = 100x (Number unable to see N8 binocularly, with near vision correction if used) / Total population
- Met Presbyopic Need (MPN) It is the measure of the distribution of spectacles for near vision in order to correct those with presbyopia to N8 or better binocularly.
  - = 100 x (Number who see N8 or better binocularly with own near-vision spectacles)/ total sample population
- Presbyopic Correction Coverage (PCC %) Measure of presbyopes using correction with spectacles in order to see N8 or better binocularly.
  - = 100x MPN / (UPN+MPN)

#### QUESTIONNAIRE BASED SURVEY

A focus group discussion was conducted in a nearby village (adjacent to the study village) before the questionnaire was prepared. It was conducted among a group of 10 males and 10 females (separately) who belonged to the village. They were asked about their daily routine and how having good vision helped them in their daily work. They were also asked if they had poor vision, how different it will be for them and what difficulties will they have in conducting these routine activities. This was conducted to find out the common activities specific to the village which helped us develop a presbyopia visual function questionnaire relevant to the population studied. The validated questionnaire from a study in a Chinese population was used and activities relevant to our south Indian population were added (13). The instruments used in this study included a 12-item Near vision related Quality Of Life Questionnaire and two items drawn from the spectacle usage section of the WHO Spectacle and Work Productivity Questionnaire(44).

Two trained social workers conducted the interview based on functional needs of presbyopia and how it affects the quality of life. The interview was conducted in Tamil, and the response was recorded in a separate form. The two interviewers were trained before the start of the study and a pilot study was conducted a week before the study. The pilot study was among 30 presbyopic individuals above 30 years of age

who presented to a peripheral camp with complaints of difficulty in near and distance vision.

Each individual was asked about how they felt about their vision and how it affected their daily routine activities. These activities included reading , writing , using a mobile phone , threading a needle , harvesting, cooking, cleaning hair of their children , helping their children with homework . Initially they were asked if they regularly conducted the activity and if 'yes' then the participants were asked to grade the difficulty in performing these activities due to their near vision . The difficulty was graded on a scale between '0-100' where '0' was no difficulty and '100' meant the person could not perform the task. This was asked in a locally understandable term. The difficulty was graded as

i) none ii) mild (1 -25%) iii) moderate (26 -50%) iv) severe (51 - 75%) v) (>75%) cannot do.

Questions were also included regarding pattern of spectacle use. This included the reason for spectacle use, if happy with vision, source of spectacle providers, if they ever had an eye check-up, barriers for spectacle use and eye check-up.

This was followed by a questionnaire based on quality of life. The participants were asked how their vision affected them in their daily activities and if it had an impact in their social life. All those participants who were deaf/mute, who had poor vision and

who were seen during the house visits were not administered the questionnaire and

thus were excluded during further analysis.

REFERRAL AND DISTRIBUTION OF SPECTACLES

Among all the participants examined, those who needed cataract surgery were referred

to the base hospital on specific dates and underwent cataract surgery. All those who

needed further evaluation were also referred to the main eye hospital. Near vision

spectacles were provided to all those who had difficulty in performing their daily

activities.

Also, among the presbyopes, 84 participants were given prescription for near vision

spectacles, out of which 24 of them collected the spectacles.

**SAMPLE SIZE CALCULATION** 

Formula

 $n = \frac{Z_{1-\alpha_{2}}^{2} p(1-p)}{d^{2}}$ 

Where,

P

: Expected proportion

d

: Absolute precision

1- α/2 : Desired Confidence level

46

4 pq / d\*d

4\*50\*50/10\*10

P = 50 %

Sample size = 100 presbyopes.

Prevalence of presbyopia 50%

So will need 200 persons over the age of 30 to get the required sample.

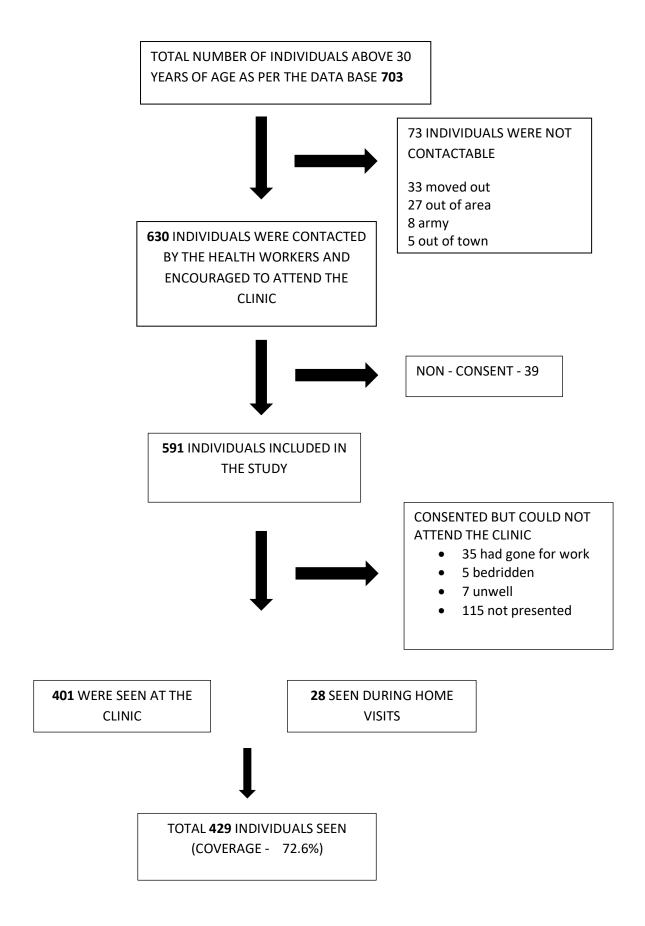
#### **STATISTICAL ANALYSIS**

Continuous variables were analysed using descriptive analysis. The demographic and other baseline characteristics like age, gender, education, occupation of subjects with and without presbyopia were compared using chi-squared tests and independent sample t-test. Prevalence was reported as such with 95 % confidence intervals. Multiple logistic regressions were done to determine the various determinants of presbyopia like age, gender, occupation, education. Also, the One-way ANOVA test and Kruskal-Wallis test were used to compare the difficulty in performing various activities with near vision.

**RESULTS** 

The total number of individuals above 30 years of age enumerated in the selected village were 703. Of the 703, 591 were finally included in the study and we examined 429 individulas (coverage of 72.6%). Of them, 401 were examined in the study clinic and 28 were covered during door to door visits.

The flow of the study conducted is shown in the figure below:



## A. DEMOGRAPHY

Among the 429 subjects examined, the mean age was 51.35 (SD13.88) years. The demographic characteristics of the examined individuals are listed in the tables below.

#### 1. GENDER:

**Table 1 – Gender distribution in the study population** 

GENDER	FREQUENCY	PERCENTAGE (%)
MALE	153	35.7
FEMALE	276	64.3
TOTAL	429	100

Majority of the participants were females.

#### 2. EDUCATIONAL STATUS

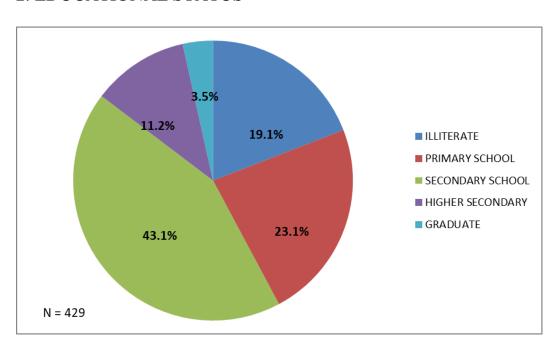


Figure 1 - Educational status of all the individuals in the study population

Most of them had received secondary school education, However one fifth were illiterate.

## 3. OCCUPATION

Majority (31.7%) of the individuals were manual labourers followed by housewives (28%).

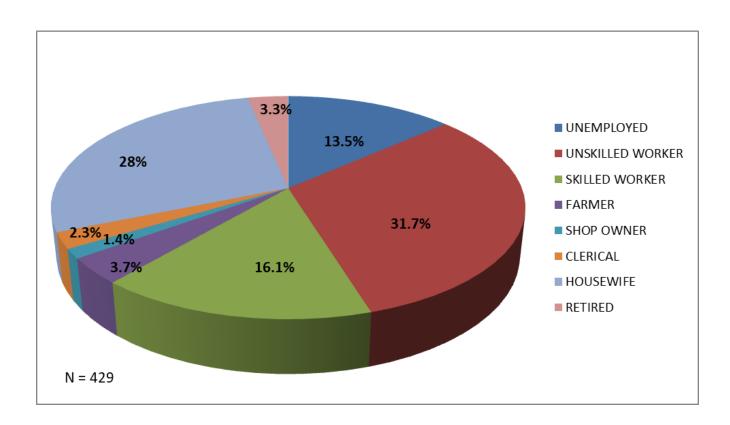


Figure 2 - The distribution of various occupation of the individuals in the study population

## 4. <u>CO - MORBIDITIES</u>

Among the various co-morbidities, 70 % of the participants had no comorbidities. Of those who did have, majority of the subjects were diagnosed with diabetes and hypertension.

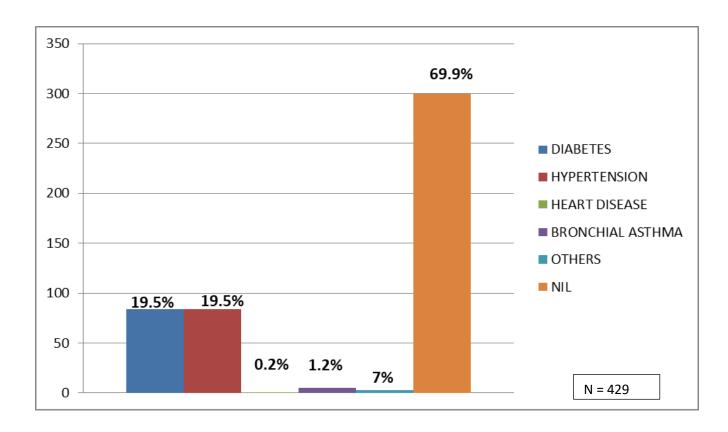


Figure 3 – Figure showing the distribution of various co-morbidities in the population.

## B. PREVALENCE OF PRESBYOPIA

The overall prevalence of presbyopia was 51.3% (CI 46.3 - 55.7%). Among the presbyopes in the study population, the mean age was 52.34 (SD 9.452), the minimum age being 35 years.

The prevalence was higher among women [61.4% (CI 56.4 – 65.6 %)] than men [38.6% (CI 33.4 – 42.6 %)].

Majority of the presbyopes were unskilled workers mostly manual labourers (33. 6%) followed by housewives and skilled workers like drivers, painters, electricians etc (27.7% and 16.4% respectively).

# B 1. PREVALENCE OF PRESBYOPIA BY AGE CATEGORIES AMONG THOSE ABOVE 30 YEARS

Table 2 - Prevalence of presbyopia by age categories among those above 30 years of age

AGE GROUP	NUMBER OF	TOTAL NUMBER IN	PERCENTAGE
	PRESBYOPES	THAT AGE GROUP	
30-40 YEARS	11	103	10.5
41-50 YEARS	102	117	87.2
51- 60 YEARS	70	90	77.8
>61 YEARS	37	119	31.09

Presbyopia was more common in the fourth decade and the prevalence decreased beyond 60 years of age.

## **B 2. DETERMINANTS OF PRESBYOPIA**

When we analysed the determinants of Presbyopia using Simple logistic regression, we found age, educational status and diabetes mellitus to be associated. The results are shown in Table 3 a.

Table 3a: Univariate analysis of the determinants of presbyopia

CHARACTERISTIC	ODDS RATIO (OR)	95% CI	<u>P</u>
AGE, PER YEAR	1.58	1.414 – 1.758	<u>&lt;.0001</u>
GENDER	0.696	0.424 - 1.144	0.153
EDUCATION	0.251	0.086 - 0.732	<u>.011</u>
OCCUPATION	0.505	<u>0.165 – 1.550</u>	0.232
DIABETIS MELLITUS	4.362	1.799 – 10.578	0.001

On multivariate analysis, after adjusting for confounders , we analysed the determinants of presbyopia by using simple logistics ,and we found that educational

status and diabetes mellitus were still significantly associated as shown in Table 3b below.

Table 3b – Multivariate analysis of the determinants of presbyopia

CHARACTERISTIC	ODDS RATIO (OR)	95% CI	<u>P</u>
GENDER	0.556	0.332 - 0.993	0.086
EDUCATION	0.210	.070 - 0.630	.005
OCCUPATION	0.642	0.198-2.083	0.460
DIABETIS MELLITUS	4.584	1.870 – 11.241	0.001

The risk of presbyopia increases with advancing age, and there is a strong association with diabetes. Also there is an increase risk among the illiterate population.

There was no association of presbyopia with gender and occupation in our study population.

## C. MET AND UNMET NEED OF PRESBYOPIA

- Among the 220 presbyopes in the study population, 50 subjects (12.7%) were using spectacles. Also among those not using spectacles (n= 161), 20 subjects (12.7%) were using spectacles earlier, and not using them now.

#### C1. UNMET PRESBYOPIC NEED (UPN)

100 X (NUMBER UNABLE TO SEE N8 BINOCULARLY, WITH NEAR VISION CORRECTION IF USED)/ TOTAL SAMPLE POPULATION = 167 / 220

= **75.8 %** 

#### C2. MET PRESBYOPIC NEED (MPN)

100 X ( NUMBER WHO SEE N8 OR BETTER BINOCULARY WITH OWN NEAR-VISION SPECTACLES)/ TOTAL SAMPLE POPULATION = 43/220

**= 19.5%** 

#### C3. PRESBYOPIC CORRECTION COVERAGE (PCC)

100 X MPN/ (MPN+UPN)

**= 20.5%** 

### D. <u>SPECTACLE USE</u>

Among the 429 individuals examined, 70 (17.2%) were using spectacles and 80% of them were happy with their vision using the present spectacles. Among them, 24(34.3%) used near vision spectacles, 13 (18.6%) used distant vision spectacles and 32 (45.7%) used bifocals.

Among the spectacle users, 58.5% were female, majority (41.4%) had completed primary education and 34.3 % of them were housewives.

Among those not using spectacle, 66.5% were females, but in contrast to the spectacle users majority (34%) of them were manual labourers

Table 4 – Distribution of spectacle use in the study population

SPECTACLE USE	FREQUENCY	PERCENTAGE
YES	70	17.2
NO	338	82.8
TOTAL	429	100

Among the participants of the study, only 17.2% of the individuals were using spectacles.

# **D 1. REASON FOR SPECTACLE USE**

Among the 70 individuals who were wearing spectacles, 45.7% of them used them for both near and distant vision (bifocals).

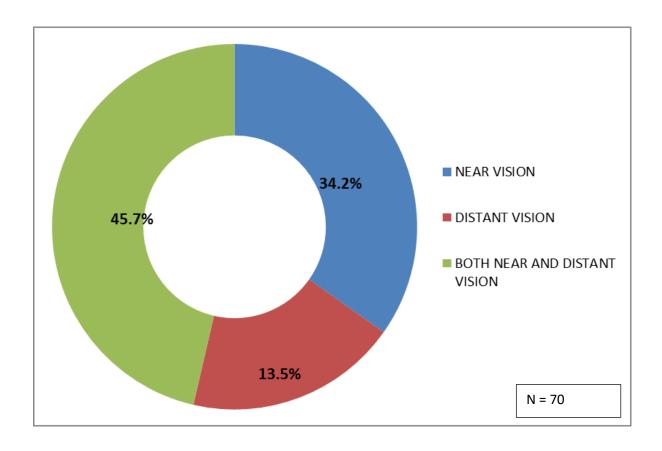


Figure 4 - Reason for spectacle use in the study population

# **D 2 . SOURCE OF SPECTACLES**

Among those who were using spectacles , 82.9% of the individuals received them from hospital eye units.

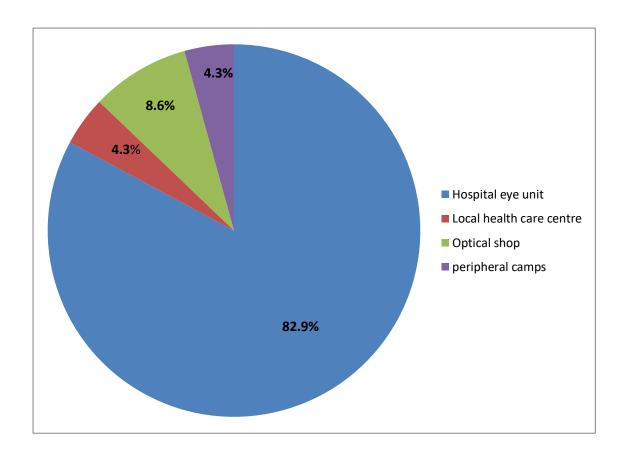


Figure 5 – The distribution of spectacle providers in the study population .

# **D 3. BARRIERS TO SPECTACLE USE**

Among the 220 presbyopes, 73.2 % of them were not using spectacles. The most common barrier to spectacle use was 'lack of felt need'.

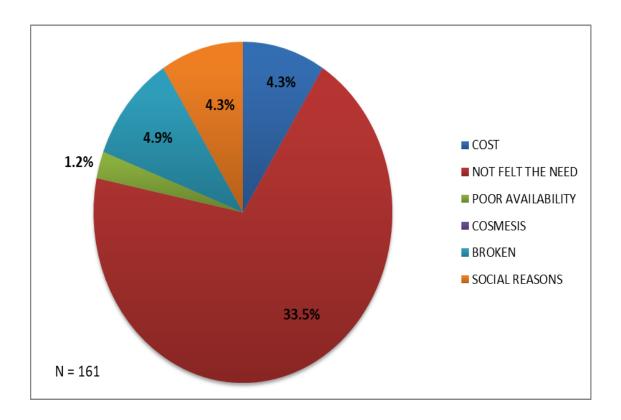


Figure 6 – The common barriers to spectacle use.

## **E. OCULAR MORBIDITY**

The below table shows the pattern of ocular morbidity in the study population.

Presbyopia is the most common morbidity followed by refractive error.

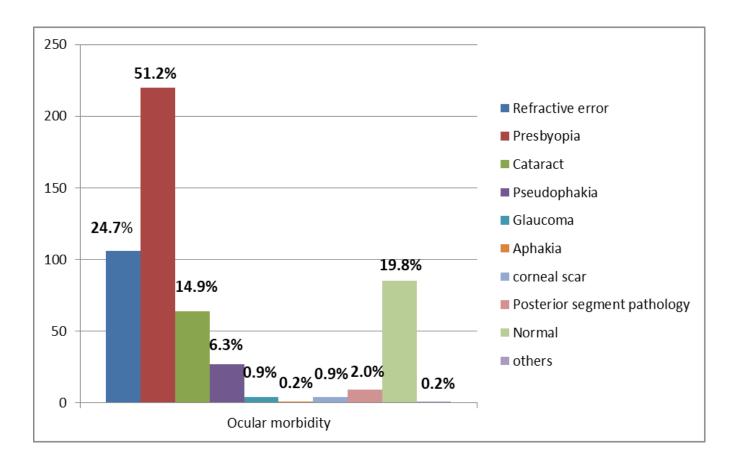


Figure 7 – Distribution of variours ocular morbidities in the study population.

## F. REFERRED PATIENTS

Among the 52 subjects who were advised to come to the base hospital for further evaluation, 28 patients came to the base hospital (Schell Eye Hospital Campus) for further treatment.

#### F 1. TREATMENT FOR REFERRED PATIENTS

The patients who were referred from the study clinic were examined at the base hospital. Treatment given to these patients is shown in the figure below.

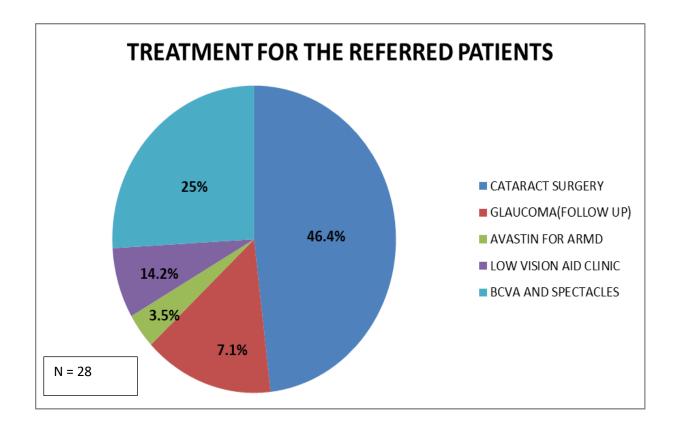


Figure 8 – Treatment provided to the patients at the base hospital .

# G. <u>CAUSE FOR DECREASE IN VISION</u>

Using WHO categorisation of presenting distance visual acuity, 242 (56.4%) had normal vision. The distribution of those with Visual impairment and blindness is shown in table (n=187).

Table 5 - The distribution and causes of visual impairment and blindness.

	NUMBER	PERCENTAGE	COMMON CAUSE
MILD VISUAL	113	26.4	REFRACTIVE ERROR
IMPAIRMENT			(60.17%)
MODERATE VISUAL	55	12.9	CATARACT
IMPAIRMENT			(56.3%)
SEVERE VISUAL	14	3.2	CATARACT
IMPAIRMENT			(71.4%)
BLINDNESS	5	1.1	POSTERIOR
			SEGMENT What %
			PATHOLOGY (60%)

## H. FUNCTIONAL STATUS

The level of difficulty in performing various tasks among the individuals in the study population is shown below. 'Threading a needle' was the most common and 'teaching children' was the least commonly performed task. The task for which majority of the individuals experience difficulty is 'threading a needle'.

Table 6 – The level of difficulty in performing various tasks

ACTIVITY	NOT DONE	NONE	MILD	MODERATE	SEVERE	CANNOT
						DO
READING	92(21.4%)	117	75(17.5%)	60(14%)	32(7.5%)	7(1.6%)
		(27.3%)				
MOBILE USE	134(31%)	157(36.6%)	49(11.4%)	26(6.1%)	20(4.7%)	1(0.2%)
CLEANING HAIR OF CHILDREN	89(20.7)	162(37.8%)	40(9.3%)	44(10.3%)	33(7.7%)	20(4.7%)
COOKING	101(23.5%)	199(46.4%)	35(8.2%)	31(7.2%)	13(3%)	6(1.4%)
THREADING NEEDLE	18(4.2%)	114(26.6%)	32(7.5%)	24(5.6%)	51(11.9%)	148(34.5%)
HARVESTING	215(50.1%)	123(28.7%)	25(5.8%)	20(4.7%)		4(0.9%)
TEACHING CHILDREN	258(60.1%)	89(20.7%)	17(4%)	13(3.0%)	9(2.1%)	1(0.2%)
LEVEL IN CONTAINER	6(1.4%)	295(67.8%)	58(13.5%)	23(5.4%)	6(1.4%)	1(0.2%)
LOCK IN DOOR		291(67.8%)	55(12.8%)	34(7.9%)	6(1.4%)	1(0.2%)
EATING		244(56.9%)	76(17.7%)	36(8.4%)	22(5.1%)	11(2.6%)

## **H 1. FUNCTIONAL IMPAIRMENT**

All the individuals in the study population were included in the questionnaire based survey. The relation between worsening of near vision and difficulty in performing various near vision related activities have been shown in the following tables and graphs.

.

## 1. THREADING A NEEDLE

The table below illustrates the near vision and the difficulty in threading a needle, and is statistically significant between the groups.

Table 7 – Near vision and difficulty in threading a needle.

DIFFICULTY	'N'	MEAN (NEAR VISION)	
NONE	113	1.10	
MILD	30	1.46	P VALUE:
MODERATE	24	1.60	0.00
SEVERE	49	1.48	
CANNOT	143	1.67	
DO			

The figure below shows the increase in difficulty in threading a needle as the near vision worsens. The graph shows that a person experiences mild difficulty when the near vision is worse than N10 and cannot perform the task when worse than N12

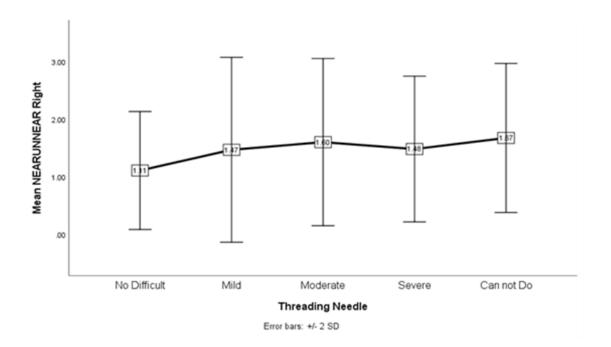


Figure 9 – The level of difficulty in threading a needle as the near vision worsens.

## 2. <u>READING / WRITING</u>

The table below illustrates the near vision and the difficulty in reading / writing, and it is statistically significant between the groups.

Table 8 – Near vision and difficulty in reading/writing

DIFFICULTY	'N'	MEAN	
		( NEAR	
		VISION )	
NONE	116	1.02	
MILD	74	1.53	P value : 0.000
			7,0000
MODERATE	55	1.70	
SEVERE	30	1.53	
CANNOT DO	7	2.29	

The graph below shows that as near vision worsens, there is increased difficulty in reading/writing, and a person experiences mild difficulty in reading/writing when near vision is less than N12 and cannot perform the task when vision is worse than N14.

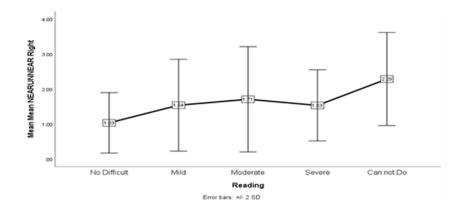


Figure 10 – Level of difficulty in reading as vision worsens.

#### 3. <u>SIGNING</u>

The table below illustrates the near vision and the difficulty in signing ,and it is statistically significant between the groups.

Table 9 – Near vision and difficulty in signing.

DIFFICULTY	'N'	MEAN (NEAR VISION)	
NONE	26	0.996	P VALUE – 0.001
MILD	9	1.40	
MODERATE	5	1.80	

The above graph shows the difficulty in signing as near vision worsens. There is mild difficulty when vision less than N10 and moderate difficulty less than N12. In this activity, there are less respondents since very few individulas performed this activity.

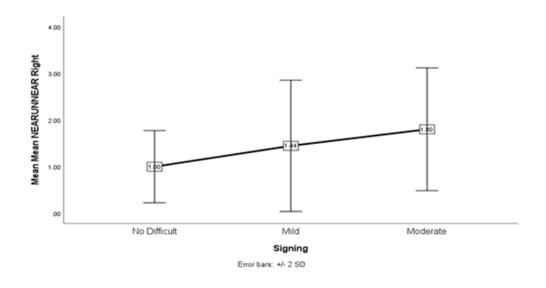


Figure 11 – Level of difficulty in signing as vision worsens.

## 4. <u>SEEING SMALL OBJECTS IN FOOD</u>

The table below illustrates the near vision and the difficulty in seeing small objects in food, and it is statistically significant between the groups.

Table 10 - Near vision and difficulty in seeing small objects in food.

DIFFICULTY	'N'	MEAN (NEAR VISION)	
NONE	240	1.32	
MILD	72	1.65	P value : 0.010
MODERATE	36	1.67	
SEVERE	22	1.94	
CANNOT DO	7	1.38	

The graph below shows that as the near vision worsens, there is increased difficulty in performing the task. The graph shows that there is difficulty in seeing objects in food when vision is worse than N12.

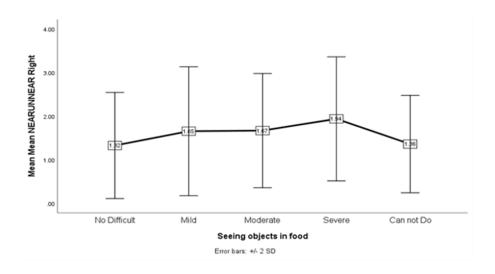


Figure 12 -Level of difficulty as the near vision worsens

## 5. CLEANING HAIR OF CHILDREN

The table below illustrates the near vision and the difficulty in performing the task, and it is statistically significant between the groups.

Table 11 – Near vision and difficulty in cleaning hair in children.

DIFFICULTY	'N'	MEAN (NEAR VISION)	
NONE	160	1.23	
MILD	39	1.56	P value : 0.000
MODERATE	41	1.53	
SEVERE	32	1.73	
CANNOT DO	19	1.75	

The graph shows that as the near vision worsens, there is increased difficulty in cleaning hair of children. The difficulty worsens when the near vision is less than N10.

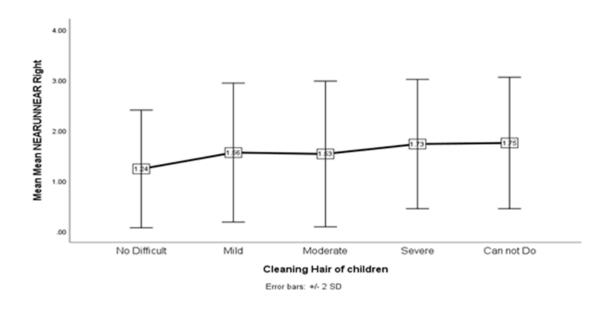


Figure 13 – Level of difficulty as near vision worsens

#### 6. COOKING

The table below illustrates the near vision and the difficulty in performing the task, and it is statistically significant between the groups.

Table 11 – Near vision and difficulty in cooking.

DIFFICULTY	'N'	MEAN	
		(NEAR VISION)	
NONE	197	1.29	
MILD	33	1.62	
MODERATE	30	1.80	
SEVERE	13	1.63	P value : 0.001
CANNOT DO	6	1.51	

The graph below shows the difficulty in performing the task as the vision worsens.

The difficulty worsens when vision is worse than N12

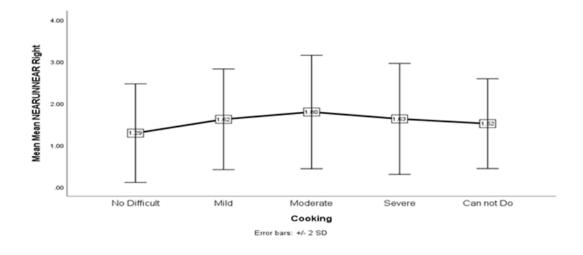


Figure 14 – Level of difficulty as near vision worsens.

The other activities that were administered in the questionnaire were teaching children at home, using mobile phones, seeing level in container and unlocking a door lock. It was observed that there is difficulty as the vision worsens, but since there were very few respondents / only few individuals performing the task, further analysis was limited.

We also compared the difficulty among the pure presbyopes and the rest of the population who had other ocular morbidities, and found that the near vision impairment is similar between the two groups.

# I. **QUALITY OF LIFE**

In the section on quality of life and social dependence, those individuals having presbyopia were more likely to report 'requiring help from others', 'diminished accomplishment due to vision' and 'feeling embarrassed/ashamed' compared to those not having presbyopia. This has been shown in the table below.

Table 12 – Impact of near vision on the quality of life

	PRESBYOPIA	NO PRESBYOPIA
	(n=220)	(n=105)
Require help from others due to vision	95 (43.1%)	13 (12.3%)
Report diminished accomplishment due to vision	27 (12.3%)	(3.8%)
Report feeling ashamed or embarrassed due to vision	(0.05%)	0

# **DISCUSSION**

This was a population based cross sectional study.

While, 703 individuals above 30 years of age were enumerated, 591 individuals were finally eligible to be included in the study, and we covered 429 subjects making the coverage 72.6%. In other population based studies on presbyopia, the coverage was 84 - 96.2% (14)

The reasons for non- participation were , being out of town/out of area ( n=73 , 17.01%), refusal (n=39, 6.1%), unwell (n=12,2%), gone for work at the time of study ( n=35, 5.9%), and not presenting to study clinic or being available for examination at home ( n=115, 19.4%).

#### A.PREVALENCE OF PRESBYOPIA

The overall prevalence of presbyopia in our study population was 51.3% (CI 46.3–55.7%), which was similar to a population based study in Andhra Pradesh (prevalence was 55.3%), but lower compared to a rural Kenyan poulation(85.4%) (14). The interpretation of prevalence is slightly different because there are minor variations in the definition of functional presbyopia and variations in age groups studied.

The mean age of presbyopia in our population was 52.34(SD9.45),. The results of our study indicate that the age of onset of presbyopia is in the fourth decade, similar

to other studies in south India done among individuals above 30 years of age (24) This result also similar to the studies from Central America and Africa(45).

The prevalence was more common among women (61.4%), similar to most of the other population based studies that showed a prevalence of 87% among females. (11–13).

There was a significant decrease of this prevalence with increase in age (14) This is probably due to other causes of decreased vision like cataract, which results in nuclear sclerosis of the lens and causes myopia (24). Also if there are other forms of cataract (eg posterior subcapsular cataract etc.) / posterior segment pathology, the near vision may be low but it will not improve with correction.

Increasing age was also associated with increase in 'plus' add to read N8 (+1.00 add for a 40 year old vs +2.50 add for a 60 year old); this was consistent with other studies (14).

#### B.RISK FACTORS OF PRESBYOPIA

Presbyopia, which is an age related condition, increases with age and is considered as an important risk factor. In our study, majority of the presbyopes were between 41 and 50 years of age, similar to a study in South India which shows an increasing trend with increasing age(24).

The age of onset of presbyopia and the associated risk factors have been studied previously. Solar radiation is considered as a major risk factor. As the average environmental temperature is higher (equatorial regions), there is an earlier onset of presbyopia (32). In our population, the earliest onset of presbyopia was seen in participants 35years of age, similar to APEDS in which it was 37 years and in contrast to other countries like Alaska (44 years), where the mean average temperature is 42 deg F.

In a multivariate model (only the presbyopic subjects) that included age,gender,occupation,education and those diagnosed with diabetes mellitus, age (OR 1.58, 95% CI 1.414-1.758) and diabetes (OR 4.58, 95% CI 1.870-11.241) had a strong association with presbyopia. Early onset of presbyopia due to decrease in amplitude of accommodation in diabetics has been described in previous studies (35) In our study population, presbyopia was associated with the illiterate individuals compared to those who are literate (OR 0.642, 95% CI 0.198– 2.083). In a study conducted in rural Tanzania, presbyopia is more common among those who are literate (12). Such an association was not found in other studies (24,36)

In previous studies, female gender was associated with presbyopia, (24) but in our study there was no association.

#### C. <u>MET AND UNMET PRESBYOPIC NEED</u>

The unmet need of presbyopia was quite high in our population, as 75.8% of those who needed spectacles for near vision, did not have them. In a similar study in the state of Andhra Pradesh, the unmet need of presbyopia was 41.9%. (46) .Other studies in Timor-leste and Kenya have reported an unmet presbyopic need of 32.3% (27) to 80% (14).

The met presbyopic need was 19.5%, higher than seen in a study done in a Kenyan rural population among those above 50 years of age where it was 5.4% (14).

The presbyopic spectacle coverage was 20.5%. This was similar to a study in Andhra Pradesh where the spectacle coverage was 23.9%(46). The coverage was higher which was higher as compared to and 19 % ,6.3% in Urban Chennai, rural Kenya respectively (4,14).

#### D. <u>SPECTACLE USE</u>

Among the presbyopes, 22.7% were using spectacles, less than other studies where 30% of the presbyopes were using spectacles (24).

Also, 20 subjects among the 220 presbyopes (12.4%) had used spectacles in the past ,but not using them now compared to 11.9% in a similar study in South India (24). We

found that the main reason (40%) for not using spectacles now was due to 'broken spectacles'. In a study done in Telengana, the most common reason for discontinuation of spectacles in persons with refractive error was 'broken spectacles'.(38)

.

The non spectacle users (among presbyopes) were mainly females (61.5%) and is similar to other studies where female gender is associated with less spectacles coverage (14,47). Women are less likely to be able to afford correction and they have to depend on someone else to purchase spectacles compared to men.(48) These differences with respect to gender represent additional challenges for presbyopia correction programmes.

Most of the spectacle users were housewives, compared to the spectacle non users who were mainly manual labourers (14,27).

Bifocals were the most common type of spectacles being used and hospital eye units being the spectacle providers, both findings being consistent with other studies where private eye clinics were primary spectacle providers (14,24,38).

The most common barrier to spectacle use among the presbyopes was 'lack of felt need', similar to a study in rural area in Telengana among presbyopes above 40 years

of age (38). Another study done in a rural village in Kenya have cited finiancial reasons as the main barrier to spectacle use (14).

.

#### E. <u>OCULAR MORBIDITY</u>

The study population included all individuals above 30 years of age. Among them, the most common morbidity was presbyopia (51.2%), followed by refractive error and cataract (24.7% and 14.9% respectively).

#### F.VISUAL IMPAIRMENT

The most common cause of mild visual impairment was uncorrected refractive error; that for moderate to severe visual impairment was cataract., similar to other population based studies (above 50 years of age) where cataract was the commonest cause for severe visual impairment (14,15) Blindness (presenting vision less than 3/60 in the better eye) constituted 1.1% of the total population, with posterior segment pathologies like retinitis pigmentosa being the commonest cause, in contrast to other studies where cataract has been reported to be the commonest cause of blindness. The number of blind patients in our study were too small to make meaningful comparisons.

Among the study population, 84 individuals were diabetic and on detailed fundus examination, only one individual was diagnosed with diabetic retinopathy (moderate diabetic retinopathy).

#### **FUNCTIONAL NEED**

This study also demonstrates that presbyopia is not only common in rural South India, but also has an impact on an individual's daily life. This was important in our population because 31.7% of the individuals were manual labourers and thus were engaged in other activities requiring near vision that did not include reading and writing.

Our primary objective was to find out at what level of near vision impairment, an individual is having difficulty in performing the tasks. Thus their near vision impairment was assessed depending on their unaided near vision ( without spectacle correction).

As expected, as the near vision worsened, the difficulty in performing the activity also increased. (13,39)

The difficulty in performing near tasks was similar at different levels of near vision between patients who were only presbyopes and those who had reduced near vision from other pathology.

There was increase in difficulty in reading, threading a needle, cleaning hair of children, seeing small objects in food and cooking with worsening of near vision.

'Threading a needle' was reported as the activity associated with greatest near-vision

related difficulty, this was similar to a previous study among a rural Kenyan population (14).

On further analysis, we looked into each activity separately and noticed that, a person who has a near vision of 'N12' or worse, had reported difficulty in performing most of the activities. In our study population, we found that among those who did not use spectacles for near vision (n=161), the most common barrier was 'lack of felt need' and 87.02% of them had vision which was N12 or better. To the best of our knowledge there are no studies reporting this to make any comparisons. This can be probably used for mass screening programmes for assessing near vision, wherein persons with a near vision acuity of N12 or worse could be encouraged to use near vision spectacles when there is functional disability. Moreover in eye camps where there is a free dispensation of near vision spectacles preference can be given to those who have a near vision of N12 or worse, assuming that the others can manage without corrective spectacles. However this was done in a rural population and near vision needs may differ in urban populations.

#### G. QUALITY OF LIFE

Those individuals who have near vision impairment have reported – requiring more help from others, feeling of diminished accomplishment due to vision and feeling ashamed due to vision compared to those who have no near vision impairment. This finding is consistent with a similar study done amongst a chinese population (13).

# **LIMITATIONS**

- Our sample size for the study was smaller compared to other similar population based studies.
- 2. All those individuals who had gone for work or were out of town at the time of examination could not be included in the study.

**CONCLUSION** 

- 1. The prevalence of presbyopia in our population was 55.3%
- 2. The unmet need of presbyopia was 75.8%, met presbyopic need 19.5% and presbyopia spectacle coverage 20.5%.
- 3. The most common barrier to spectacle use among the presbyopes was 'lack of felt need'.
- 4. As a part of the functional need assessment, we reported increase difficulty in performing near vision tasks as the near vision worsened. Also, most of the individuals reported difficulty as the near vision worsens below N12.
- 5. In the quality of life assessment, presbyopic individuals reported 'needing help from others due to vision', 'feeling ashamed /embarrassed due to vision', 'reduced accomplishment due to decrease vision' compared to those who do not have presbyopia.
- The most common ocular morbidity in our study group was presbyopia
   (51.2%) and the most common cause for moderate to severe visual impairment was cataract.

# REFERENCES

- 1. Bourne RRA, Stevens GA, White RA, Smith JL, Flaxman SR, Price H, et al. Causes of vision loss worldwide, 1990-2010: a systematic analysis. Lancet Glob Health. 2013 Dec;1(6):e339-349.
- Magnitude, temporal trends, and projections of the global prevalence of blindness and distance and near vision impairment: a systematic review and meta-analysis - The Lancet Global Health [Internet]. [cited 2019 Oct 30]. Available from: https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(17)30293-0/fulltext
- 3. Neena J, Rachel J, Praveen V, Murthy GVS, for the RAAB India Study Group. Rapid Assessment of Avoidable Blindness in India. Myer L, editor. PLoS ONE. 2008 Aug 6;3(8):e2867.
- 4. Marmamula S, Narsaiah S, Shekhar K, Khanna RC, Rao GN. Visual Impairment in the South Indian State of Andhra Pradesh: Andhra Pradesh Rapid Assessment of Visual Impairment (APRAVI) Project. PLOS ONE. 2013 Jul 23;8(7):e70120.
- 5. Vision impairment and blindness [Internet]. [cited 2019 Nov 1]. Available from: https://www.who.int/news-room/fact-sheets/detail/blindness-and-visual-impairment
- 6. Holden BA. Blindness and poverty: a tragic combination. Clin Exp Optom. 2007 Nov;90(6):401–3.
- 7. Universal eye health: a global action plan 2014-2019. Geneva: World Health Organization; 2013
- 8. Resnikoff S. Global magnitude of visual impairment caused by uncorrected refractive errors in 2004. Bull World Health Organ. 2008 Jan 1;86(1):63–70.
- 9. Fricke TR, Tahhan N, Resnikoff S, Papas E, Burnett A, Ho SM, et al. Global Prevalence of Presbyopia and Vision Impairment from Uncorrected Presbyopia: Systematic Review, Meta-analysis, and Modelling. Ophthalmology. 2018;125(10):1492–9.
- 10. Schachar RA. The mechanism of accommodation and presbyopia. Int Ophthalmol Clin. 2006;46(3):39–61.
- 11. Holden BA, Fricke TR, Ho SM, Wong R, Schlenther G, Cronjé S, et al. Global vision impairment due to uncorrected presbyopia. Arch Ophthalmol. 2008;126(12):1731–1739.
- 12. Burke AG, Patel I, Munoz B, Kayongoya A, McHiwa W, Schwarzwalder AW, et al. Population-based study of presbyopia in rural Tanzania. Ophthalmology. 2006 May;113(5):723–7.
- 13. Lu Q, He W, Murthy GVS, He X, Congdon N, Zhang L, et al. Presbyopia and Near-Vision Impairment in Rural Northern China. Invest Ophthalmol Vis Sci. 2011 Apr 1;52(5):2300–5.
- 14. Sherwin JC, Keeffe JE, Kuper H, Islam FMA, Muller A, Mathenge W. Functional presbyopia in a rural Kenyan population: the unmet presbyopic need. Clin Experiment Ophthalmol. 2008 Apr;36(3):245–51.
- 15. Troncoso MU. Theories of Accommodation. Am J Ophthalmol. 1928 Dec 1;11(12):976–9.

- 16. 01. Helmholtz H. Über die Akkomodation des Auges. Albrecht von Graefes Arch Klin Expl Ophtalmol 1855;1(1):1-89. [Internet]. Points de Vue | International Review of Ophthalmic Optics. [cited 2019 Sep 10]. Available from: /01-helmholtz-h-uber-die-akkomodation-desauges-albrecht-von-graefes-arch-klin-expl-ophtalmol-1855111
- 17. Murray CJL, editor. The global burden of disease: a comprehensive assessment of mortality and disability from diseases, injuries, and risk factors in 1990 and projected to 2020; summary. Cambridge: Harvard School of Public Health [u.a.]; 1996. 43 p. (Global burden of disease and injury series).
- 18. Gupta N, Vashist P, Malhotra S, Senjam SS, Misra V, Bhardwaj A. Rapid Assessment of Visual Impairment in Urban Population of Delhi, India. Griffiths UK, editor. PLOS ONE. 2015 Apr 27;10(4):e0124206.
- Sheeladevi S, Seelam B, Nukella PB, Borah RR, Ali R, Keay L. Prevalence of refractive errors, uncorrected refractive error, and presbyopia in adults in India: A systematic review. Indian J Ophthalmol. 2019 May 1;67(5):583.
- 20. Milder B. Presbyopia. Recent Research and Reviews From the Third International Symposium. Am J Ophthalmol. 1988 Feb 1;105(2):222.
- 21. WPA2015\_Report.pdf [Internet]. [cited 2019 Sep 10]. Available from: https://www.un.org/en/development/desa/population/publications/pdf/ageing/WPA2015\_Report.pdf
- 22. Flaxman SR, Bourne RRA, Resnikoff S, Ackland P, Braithwaite T, Cicinelli MV, et al. Global causes of blindness and distance vision impairment 1990–2020: a systematic review and meta-analysis. Lancet Glob Health. 2017 Dec;5(12):e1221–34.
- 23. Zebardast N, Friedman DS, Vitale S. The prevalence and demographic associations of presenting near-vision impairment among adults living in the United States. Am J Ophthalmol. 2017 Feb;174:134–44.
- 24. Nirmalan PK, Krishnaiah S, Shamanna BR, Rao GN, Thomas R. A Population-Based Assessment of Presbyopia in the State of Andhra Pradesh, South India: The Andhra Pradesh Eye Disease Study. Invest Ophthalmol Vis Sci. 2006 Jun 1;47(6):2324–8.
- 25. Marmamula S, Narsaiah S, Shekhar K, Khanna RC. Presbyopia, spectacles use and spectacle correction coverage for near vision among cloth weaving communities in Prakasam district in South India. Ophthalmic Physiol Opt J Br Coll Ophthalmic Opt Optom. 2013 Sep;33(5):597–603.
- 26. Marmamula S, Keeffe JE, Rao GN. Uncorrected Refractive Errors, Presbyopia and Spectacle Coverage: Results from a Rapid Assessment of Refractive Error Survey. Ophthalmic Epidemiol. 2009 Jan 1;16(5):269–74.
- 27. Ramke J, du Toit R, Palagyi A, Brian G, Naduvilath T. Correction of refractive error and presbyopia in Timor-Leste. Br J Ophthalmol. 2007 Jul;91(7):860–6.
- 28. Hickenbotham A, Roorda A, Steinmaus C, Glasser A. Meta-Analysis of Sex Differences in Presbyopia. Invest Ophthalmol Vis Sci. 2012 May 1;53(6):3215–20.
- 29. Pointer JS. Broken down by age and sex. The optical correction of presbyopia revisited. Ophthalmic Physiol Opt. 1995 Sep 1;15(5):439–43.

- 30. Hofstetter HW. A survey of practices in prescribing presbyopic adds. Am J Optom Arch Am Acad Optom. 1949 Apr;26(4):144–60.
- 31. Millodot M, Millodot S. Presbyopia correction and the accommodation in reserve. Ophthalmic Physiol Opt J Br Coll Ophthalmic Opt Optom. 1989 Apr;9(2):126–32.
- 32. Miranda MN. The geographic factor in the onset of presbyopia. Trans Am Ophthalmol Soc. 1979;77:603–21.
- 33. Dische Z, Bartels GC. Some biochemical aspects of light effects on transparent eye tissues. Ann Ophthalmol. 1975 Feb;7(2):165–70.
- 34. Kidd Man RE, Fenwick EK, Sabanayagam C, Li L-J, Gupta P, Tham Y-C, et al. Prevalence, Correlates, and Impact of Uncorrected Presbyopia in a Multiethnic Asian Population. Am J Ophthalmol. 2016 Aug 1;168:191–200.
- 35. Adnan, Efron N, Mathur A, Edwards K, Pritchard N, Suheimat M, et al. Amplitude of Accommodation in Type 1 Diabetes. Invest Ophthalmol Vis Sci. 2014 Oct 1;55(10):7014–8.
- 36. Chiroma MR, Jamda AM. Impact of Uncorrected Presbyopia on the Quality of Life in Rural Gwagwalada, Nigeria. J Community Med Prim Health Care. 2017 Jan 1;29(1):68-73–73.
- 37. Seidu. Presbyopic spectacle coverage and barriers to near vision correction among adult population in ido local government area, Southwest Nigeria [Internet]. [cited 2019 Oct 7]. Available from: http://www.jcsjournal.org/article.asp?issn=2468-6859;year=2017;volume=14;issue=4;spage=188;epage=192;aulast=Seidu
- 38. Marmamula S, Khanna RC, Kunuku E, Rao GN. Spectacles use in a rural population in the state of Telangana in South India. Indian J Ophthalmol. 2017 Jun;65(6):509–15.
- 39. Patel I, Munoz B, Burke AG, Kayongoya A, McHiwa W, Schwarzwalder AW, et al. Impact of presbyopia on quality of life in a rural African setting. Ophthalmology. 2006 May;113(5):728–34.
- 40. McDonnell PJ, Lee P, Spritzer K, Lindblad AS, Hays RD. Associations of presbyopia with vision-targeted health-related quality of life. Arch Ophthalmol Chic III 1960. 2003 Nov;121(11):1577–81.
- 41. Frick KD, Joy SM, Wilson DA, Naidoo KS, Holden BA. The Global Burden of Potential Productivity Loss from Uncorrected Presbyopia. Ophthalmology. 2015 Aug;122(8):1706–10.
- 42. Pesudovs K, Burr JM, Harley C, Elliott DB. The development, assessment, and selection of questionnaires. Optom Vis Sci Off Publ Am Acad Optom. 2007 Aug;84(8):663–74.
- 43. Likert R. A technique for the measurement of attitudes. Arch Psychol. 1932;22 140:55–55.
- 44. Reilly M. Work Productivity and Activity Impairment Questionnaire: :2.
- 45. Kamali A, Whitworth JA, Ruberantwari A, Mulwanyi F, Acakara M, Dolin P, et al. Causes and prevalence of non-vision impairing ocular conditions among a rural adult population in sw Uganda. Ophthalmic Epidemiol. 1999 Mar;6(1):41–8.

- 46. Marmamula S, Ravuri LVCS, Boon MY, Khanna RC. Spectacle coverage and spectacles use among elderly population in residential care in the south Indian state of Andhra Pradesh. BioMed Res Int. 2013;2013:183502.
- 47. Correction of refractive error in the adult population of Bangladesh: meeting the unmet need. PubMed NCBI [Internet]. [cited 2019 Nov 3]. Available from: https://www.ncbi.nlm.nih.gov/pubmed/14744879
- 48. Patel I, West S. Gender differences in presbyopia. Community Eye Health. 2009 Jun;22(70):27.

# **APPENDIX**

- (i) IRB APPROVAL LETTER
- (ii) PATIENT INFORMATION SHEET ENGLISH
- (iii) INFORMED CONSENT ENGLISH, TAMIL
- (iv) DATA COLLECTION SHEET
- (v) DATA

#### APPENDIX (i)

#### IRB APPROVAL LETTER



### OFFICE OF RESEARCH INSTITUTIONAL REVIEW BOARD (IRB) CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

Dr. B.J. Preshanthum, M.A., M.A., Dr. Min (Closus) Director, Christian Counseling Center, Chairperson, Ethics Committee.

Dr. Anna Benjamin Pulimood, M.S.B.S., MD., Ph.D. Chairperson, Research Committee & Principal

Dr. Biju George, MBBS, MD, DM. Deputy Chairperse Secretary, Ethics Committee, IRB Additional Vice-Principal (Research)

November 26, 2018

Dr. Divya Giridhar,, PG Registrar, Department of Ophthalmology, Christian Medical College, Vellore - 632 002.

Sub: Fluid Research Grant: New Proposal:

Prevalence of unmet need and functional status of rural south Indian adults with presbyopia a cross sectional study.

Dr. Divya Giridhar (Emp. No. 21418), PG Registrar, Ophthalmology, Dr. Padma Paul (emp. No. 14374, Dr. Anika Amritanand (emp. No. 32301, Ophthalmology, Dr. Vinod Abraham (Emp. No. 28095), Community Health.

Ref: IRB Min. No. 11357 [OBSERVE] dated 04.06.2018

Dear Dr. Divya Giridhar,

I enclose the following documents:-

Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Biju George, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Biju George

Dr. Biju George

Secretary (Ethics Committee)

Institutional Review Broad

Christian Medical Conega, volora 631 002.

Dr. BIJU GEORGE

1 of 4



# OFFICE OF RESEARCH INSTITUTIONAL REVIEW BOARD (IRB) CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

Dr. B.J. Pyashantham, M.A., M.A., Dr. Mis (Clinical) Director, Christian Counseling Center, Chairperson, Ethics Committee. Dr. Anna Benjamin Pulimood, M.B.S., MD., Ph.D., Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM., Deputy Chairperson, Secretary, Ethics Committee, IRB Additional Vice-Principal (Research)

November 26, 2018

Dr. Divya Giridhar,, PG Registrar, Department of Ophthalmology, Christian Medical College, Vellore – 632 002.

Sub: Fluid Research Grant: New Proposal:

Prevalence of unmet need and functional status of rural south Indian adults with presbyopia a cross sectional study.

Dr. Divya Giridhar (Emp. No. 21418), PG Registrar, Ophthalmology, Dr. Padma Paul (emp. No. 14374, Dr. Anika Amritanand (emp. No. 32301, Ophthalmology, Dr. Vinod Abraham (Emp. No. 28095), Community Health.

Ref: IRB Min. No. 11357 [OBSERVE] dated 04.06.2018

Dear Dr. Divya Giridhar,

The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Prevalence of unmet need and functional status of rural south Indian adults with presbyopia a cross sectional study" on June 04, 2018.

The Committee reviewed the following documents:

- 1. IRB application format
- 2. Proforma
- 3. Questionnaire (English and Tamil)
- 4. Consent Form and Information Sheet (English and Tamil)
- Cvs of Drs. Divya Giridhar, Padma Paul, Anika Amritanand, Vinod Abraham
- 6. No. of documents 1-5

The following Institutional Review Board (Blue, Research & Ethics Committee) members were present at the meeting held on June 04th 2018 in the New IRB Room, Bagayam, Christian Medical College, Vellore 632 004.



# OFFICE OF RESEARCH INSTITUTIONAL REVIEW BOARD (IRB) CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

Jr. B.A. Productions, M.A. M.A. Dr. Min (Closes) Surror, Christian Counciling Contes, Surpossus, Editor Committee.

Dr. Anna Boojamin Pulimood, MARS, MD, PaD, Chairpetson, Research Committee & Principal

Dr. Biju George, St. B.S., MD., 286, Dapaty Chairperson, Sacretary, Ethics Commissee, IRD Additional Vice-Principal (Research)

Name	Qualification	Designation	Affiliation
Dr. Biju George	MBBS, MD, DM	Professor, Hazenatology, Research), Additional Vice Principal, Deputy Chairperson (Research Committee), Member Secretary (Ethics Committee), IRB, CMC, Vellere	Jacomesi, Clinicias
Rev. Joseph Deveraj	BSc, BD	Chaplaincy Department, CMC, Vallore	Social Scientist
Dr. B. J. Prashantham	MA(Counseling Psychology), MA(Theology); On Min(Clinical Counselling)	Chairperson, Ethics Committee, IRB. Director, Christian Courseling Centre, Vellore	Externol, Social Scientist
Or. Anusafta Rose	MBBS, MD, MHSC (Binethics)	Associate Professor, Community Health, CMC, Vallore	Internal, Clinicius
Dr. Thomas V Paul	MBBS, MD, DNB, PhD	Professor, Endocrinology, CMC, Vollere	Internal, Clinician
Mr. C. Sampath	BSc, Bli	Advocata, Vellore	External, Legal Expert
or. Jayaprakash duliyil	BSc, MBBS, MD, MPH, Dr PH (Epid), DMHC	Retired Professor, CMC, Vellare	External, Scientist &Epidemiologist
ds. Grace Rebekha	M.Sc., (Biostatistics)	Lecturer, Biostatistics, CMC, Vellore	Internal, Statistician
dr. Samuel Abraham	MA, PGDBA, PGDPM, M. PMI, BL.	Sr. Legal Officer, CMC, Vellore	Internal, Legal Expert
Dr. RapeaPrablus	MBBS, MD (Pharma)	Associate Professor, Clinical Phermacology, CMC, Vellore	Internal, Pharmacologist
Mrs. Pattabiraman	BSc, DSSA	Social Worker, Vollow	External, Lay Person
Mrs. Shoela Ducal	MSc Nursing	Professor, Medical Surgical Nursing, CMC, Vellore	Internal, Nerse

IRB Min, No. 11357 [OBSERVE] dated 04.06.2018

des Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellare, Tamil Nado 612 002 Del 0416 - 1284294, 2284202 Fax: 0416 - 2262788, 2284481 E-mail encearch@concretierc.ac.is



## OFFICE OF RESEARCH INSTITUTIONAL REVIEW BOARD (IRB) CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

Dr. B.J. Prachantham, M.A., M.A., Dr. His (Cinical) Director, Christian Counseling Center, Chairperson, Ethics Committee.

Dr. Anna Benjamin Pulimood, M.B.S., MD., Ph.D., Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD. DM., Deputy Chairperson, Secretary, Ethics Committee, IRB Additional Vice-Principal (Research)

Dr. Tunny Sebastian	P.hd., (Biostatistics)	Lecturer, Biostatistics, CMC, Vellore	Internal, Statistician
Mrs. Nirmala Margaret	MSc Nursing	Addl. Deputy Nursing Superintendent, College of Nursing, CMC, Vellore	Internal, Nursc
Dr. Sathish Kumar	MBBS, MD, DCH	Professor, Child Health, CMC, Vellore	Internal, Clinician
Dr. Barney Isaac	M.B.,B.S. D.N.B (Respiratory Diseases)	Associate Professor, Pulmonary Medicine, CMC, Vellore	Internal, Clinician
Dr. John Antony Jude Prokash	MBBS, MD	Professor, Clinical Microbiology, CMC, Vellore.	Internal, Clinician.
Dr. AjithSivadasan	MD, DM	Professor, Neurological Sciences, CMC, Vellore	Internal, Clinician
Dr. RekhaPai	BSc, MSc, PhD	Associate Professor, Pathology, CMC, Vellore	Internal, Basic Medical Scientist
Dr SnehaVarkki	MBBS, DCH, DNB	Professor, Paedintries, CMC, Vellore	Internal, Clinician

We approve the project to be conducted as presented.

Kindly provide the total number of patients enrolled in your study and the total number of Withdrawals for the study entitled: "Prevalence of unmet need and functional status of rural south Indian adults with presbyopia a cross sectional study" on a monthly basis. Please send copies of this to the Research Office (research@cmcvellore.ac.in).

Fluid Grant Allocation:

A sum of 50,000/- INR (Rupees Fifty Thousand Only) will be granted for I year,

Yours sincerely

Dr. Biju George

Secretary (Ethics Committee) Institutional Review Board

Dr. BIJU CEORGE

MBBS., MD., E.N.
SECRETARY - (ETHICS COMMITTEE)
Instrutional Review Board,
Christian Medical College, Vellore - 612 092

IRB Min. No. 11357 [OBSERVE] dated 04.06.2018

4 of 4

## (ii)\_PATIENT INFORMATION SHEET

#### PATIENT INFORMATION (ENGLISH)

STUDY TITLE: Prevalence of unmet need and functional status of rural South Indian adults with Presbyopia— a cross sectional study

You are invited to take part in this research study carried out in Kanyambadi block, CHAD hospital, Christian Medical College, Vellore. The information in this document is intended to enable you to choose whether or not to participate in this study.

Before participating, clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as 'Informed Consent'.

It is not mandatory to take part in this study and your decision to not take part will not affect your future medical care.

You can change your decision about partaking in the study whenever you like. Regardless of whether the study has begun, you can in any case quit.

#### WHAT IS THE PURPOSE OF THIS STUDY?

One of the important causes of avoidable blindness is uncorrected refractive error. Refractive error is a condition where we are not able to see the object clearly, and improves with the use of spectacles.

Presbyopia is another common cause of visual impairment, mainly among persons above 30 years of age. Presbyopia is mainly due to age related changes in the lens, due to which we develop difficulty in seeing near objects. It can easily be corrected by simple eye test and therefore should not remain undetected and untreated.

In this study all individuals will have a routine vision assessment followed by a full eye examination. Any individuals with presbyopia will be further interviewed based on a questionnaire which includes information regarding spectacle use and near vision tasks.

#### WHY HAVE I BEEN CHOSEN?

You have been chosen because you are above 30years and may have a problem with near vision (presbyopia). If you are diagnosed to have presbyopia and you need treatment, it will be started whether you decide to take part in the study are not. It would help us in doing the study if you consent to enrol in the study.

#### WHAT WILL HAPPEN IF I TAKE PART?

If you take part in the study, you will be requested to provide the required clinical information, undergo routine eye examinations and the required clinical investigations, all of which are non-invasive.

#### **EXPENSES AND PAYMENTS?**

There are no additional expenses or payments.

#### WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

Each participant in this study will have a vision assessment, both for near and distance, followed by basic eye examination. They will also be assessed for functional near vision problem and if any participant who is examined in the clinic needs further evaluation and treatment, they will be referred to CHAD hospital or Schell Eye Hospital campus for further treatment, investigations will be provided, if required, free of cost.

#### WHAT ARE THE POSSIBLE RISKS OF TAKING PART?

There are no risks involved in taking part in this study. All the examination procedures and tests to be done are completely non-invasive and pain free.

#### WILL MY TAKING PART BE KEPT CONFIDENTIAL?

All patient information is stored on password protected computer databases and in locked filing cabinets and will only be accessible to the research team.

#### WHAT IF THERE IS A PROBLEM?

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you can contact the Principal Investigator or the Research Office at Carman Block, Bagayam, Vellore, 632002, email - research@cmcvellore.ac.in or researchothers@cmcvellore.ac.in, phone - 0416 2284294.

#### WHAT WILL HAPPEN TO ANY TEST RESULTS I GIVE?

The test results will be kept safe in the hospital's patient information databases, which are password protected and accessible to only the members of the research team, who are medical professionals.

#### HOW WILL THE INFORMATION I PROVIDE BE USEFUL?

We plan to analyze the information collected and understand the condition, that is, presbyopia, in a better way. We will then publish the results in a health journal so others can read about it and learn from the results of the study, so that the new found information may be used to benefit others, world over. The personal information collected will still remain strictly confidential, and only the interpretations of the data will be published.

#### WHO HAS REVIEWED THIS STUDY?

The Institutional Review Board (IRB) of the Christian Medical College, Vellore, has reviewed this study.

You have the right to confidentiality regarding the privacy of your medical information (personal details, results of physical examinations, investigation and your medical history). By signing this document, you will be allowing the research team investigators, if required, to access your medical information.

The results of clinical tests and therapy performed as part of this research may be included in your medical record. The information from this study, if published in scientific journals or presented at scientific meetings, will not reveal your identity.

Thank you for reading this.

If you agree to enter the study, please sign the attached consent form.

Contact Person (Principal Investigator)

DR. DIVYA GIRIDHAR

Designation: P.G.Registrar

Department of Ophthalmology

Department of Ophthalmology, Schell Eye Hospital,

CMC, Vellore

Phone Numbers: 9791296321

Email ID: divg1212@gmail.com

#### Patient Information Sheet - Tamil

#### <u>அத்திக்கப்பட்ட முடிவு</u>

#### தேவையான தகவல்

**படிப்பத் தலைப்பு** கிராமப்புற தென்னிந்திய வயதினர்களின் அடக்கமான தேவை மற்றும் செயல்பாட்டு நிலை ஆகியவற்றின் பிரசன்னம் **அதகில் உள்ள பார்வை** (Presbyopia / near vision)-குறுக்கு வெட்டு ஆய்வு

கன்பப்பாடி தொகுதி, சேட் மருத்துவமனையில், வேலூர் மாவட்டத்தின் கிரிஸ்துவர் மருத்துவக் கல்லூரியில் மேற்கொள்ளப்பட்ட இந்த ஆராய்ச்சிப் பணிகளில் பங்கேற்க வேண்டுமா இல்லையா என்பதைத் தெரிந்துகொள்ள இந்த ஆவணம் உங்களைத் தூண்டுகிறது.

இந்த ஆய்வில் பங்கு பெறுவதற்கு முன்பாக, ஆபத்துக்கள் மற்றும் பலன்களைப் புரிந்துகொள்வதற்கு இந்த செயல்முறை 'தகவலரிந்த ஒப்புதல்' என்று அழைக்கப்படுகிறது.

இந்த ஆய்வில் பங்கு பெற வேண்டியது அவசியமில்லை மற்றும் பங்கேற உங்கள் முடிவு உங்கள் எதிர்கால மருத்துவ சேவையை பாதிக்காது.

நுங்கள் விரும்பும் பேதெல்லாம் படிப்பதில் பங்கெடுப்பது பற்றி உங்கள் முடிவை மாற்றிக்கொள்ளனம்.

#### இத்த படிப்பின் தோக்கம் என்ன?

தவிர்க்கக்கூடிய குருட்டுத்தன்மைக்கு முக்கிய காரணங்கள் ஒன்று தவறான திரிக்கப்பட்ட பிழை. ஒளிவிலகல் பிழை என்பது பொருள் தெளிவாகக் காண முடியாத நிலைபில் உள்ளது, கண்ணாடிகளை பயன்படுத்துவதன் மூலம் அதிகரிக்கிறது.

கிட்டத்தட்ட 30 வயதுக்கு மேனன நடர்களிடையே பார்வை குறைபாட்டிற்கான மற்றொரு பொதுவான காரணியாக உள்ளது. அருகில் உள்ள பார்வை லென்னில் வயது தொடர்பான மாற்றங்களைக் கொண்டிருப்பதால் முக்கியமாக, அருகில் உள்ள பொருட்களைக் கண்டறிவதில் சிரமம் ஏற்படுவதால். எனிமையான கண் பரிசோதனை மூலம் எனிதில் சரிசெய்ய முடியும், எனவே கண்டறியப்படாத மற்றும் சிகிச்சையனிக்கப்படாமல் இருத்தல் கூடாது.

இந்த ஆட்டில் அனைத்து நபர்களும் ஒரு வழக்கமான பார்வை மதிட்டூட்டைப் பெறுவார்கள். அருகில் உள்ள பார்வை கொண்ட நபர்கள் மேலும் வினாக்கலை அடிப்படையாகக் கொண்டு நேர்காணல் செய்யப்படுவார்கள்.

#### தான் ஒன் தேர்ந்தெடுக்கப்பட்டேன்?

நாங்கள் 30years பேலே என்பதாலும் அருகே பார்வை (அருகே தொலைநோக்கு) ஒரு பிரச்சனை இருக்கனம் என்பதால், நாங்கள் அருகில் பார்வை வேண்டும் கண்டநியப்பட்டுள்ளனர் பெண்றனக்கு நாங்கள் சிகிச்சை தேவைப்படுகிறது அது நாங்கள் இல்லை ஆப்வில் பங்கேற்க முடிவு என்பதை ஆரம்பிக்கப்படும் நாங்கள் தேர்வு வருகின்றன . ஆப்வில் சேர ஒப்புக்கொண்டால், அதைப் படிப்பதில் நமக்கு இது நதவும்.

#### நான் பங்கு பெற என்ன நடக்கும்?

இந்த ஆய்வில் பக்கேற்க நூக்கள் தேவையான மருத்துவ தகவல்களை வழங்க வேண்டும், வழக்கமான கண் பரிசோதனைகள் மற்றும் தேவையான மருத்துவ ஆய்வுகளுக்கு உட்படுத்தப்பட வேண்டும், இவை அனைத்தையும் ஊடுருவுகின்றன.

#### செலவுகள் மற்றும் பணம்?

கூடுதல் செலவுகள் அல்லது பணம் இல்லை.

#### எடுத்துக் கொள்ளக்கூடிய சாத்தியக்கூறுகள் என்ன?

இந்த ஆய்வில் ஒவ்வொரு பங்கேற்பாளரும் தொலைநோக்கு மற்றும் தொலைநோக்கு ஆகியவற்றிற்கான பார்வை மதிப்பட்டைக் கொண்டிருக்க வேண்டும், அதன்பின் அடிப்படை கண் பரிசோதனை மேற்கொள்ளப்படும். பார்வை பிரச்சனைக்குள்ளாக செயல்படுவதற்கு அவர்கள் மதிப்படு செய்யப்படுவார்கள், மேலும் மருத்துவத்தில் பரிசோதிக்கப்பட்ட எந்தவொரு நபரும் மேலும் மதிப்படு மற்றும் சிகிச்சை தேவைப்பட்டால், அவர்கள் CHAD மருத்துவமனை அல்லது Schell கண் மருத்துவமனை வளாகத்திற்கு மேலும் சிகிச்சைக்காக . தேவைப்பட்டால், விசாரணைகள் இவவசமாக வழங்கப்படும்,.

#### எடுத்துக் கொள்ளக்கூடிய சாத்தியக்கூறுகள் என்ன?

இந்த ஆய்வில் பங்கு பெறுவதில் எந்த ஆபத்தும் இல்லை. அனைத்து பரிசோதனை நடைமுறைகள் மற்றும் சோதனைகள் செய்யப்பட வேண்டும் முற்றிலும் இலவசம்.

#### என்னால் பொதப்பேற்க இபணது?

அனைத்து நோயாளிகளும் கடவுச்சொல் பாதுகாக்கப்பட்ட கணினி தரவுத்தனங்களில் சேமிக்கப்பட்டு பூட்டப்பட்ட தாக்கல் கேபினெட்டுகளில் சேமிக்கப்படும் மற்றும் ஆராய்ச்சி குழுவிற்கு மட்டுமே அணுக முடியும்.

#### **२०५ ध्रिकंक्टन वर्त्वप्राप्ते वर्त्वस**?

இந்த ஆய்வின் போது நுங்கள் அணுகப்பட்ட அல்லது சிகிச்சையளிக்கப்பட்ட வழியின் எந்தவொரு அம்சத்தையும் பற்றி புகார் செய்ய விரும்பினால், நுங்கள் காரன் பிளாக், பாக்டம், வேலூர், 632002, மின்னஞ்சலில் முதன்மையான ஆராய்ச்சியாளர் அல்லது ஆராய்ச்சி அலுவலகத்தை தொடர்பு கொள்ளனம் - ஆராம்ச்சி @ cmcvellore.ac.in அன்னு researchothers@cmcvellore.ac.in, தொலைப்பி - 0416 2284294.

#### எந்த டெஸ்ட் முடிவுகளை நாள் பெற்றுக்கொள்வேன்?

சோதனை முடிவுகள் மருத்துவமனையின் நோயாளியின் தகவல் தரவுத்தளங்களில் பாதுகாப்பாக வைக்கப்படும், இது கடவுச்சொல் பாதுகாக்கப்பட்டு, மருத்துவ நிபுணர்களாக இருக்கும் ஆராட்ச்சி குழுவின் உறுப்பிணர்களுக்கு மட்டுமே அணுகக்கபடியதாக இருக்கும்.

#### நான் படன்படுத்தம் தகவகை எட்டி படன்படுத்துவது?

நாம் சேகரித்த தகவலை பதப்பாட்டி செப்ப திட்டமிட்டு, அந்த சூழ்நிலையை புரிந்துகொள்ளோம் , இது ஒரு சிறத்த வழியில் பாள்வைக்கு அருகில் உள்ளது பிற்பாடு, ஒரு அறோக்கியமான இதழில் முடிவுகளை வெளியிடுவோம், எனவே மற்றவர்கள் இதைப் பற்ற படிக்கவும், படிப்பிற்கான முடிவுகளில் இருந்து கற்றுக்கொள்ளவும், புதிய கண்டுபிடிப்புகள் மற்றவர்களுக்கும் பயணளிக்கும் வகையில் பயண்படுத்தப்படனம். சேகரிக்கப்பட்ட தனிப்பட்ட தகவைகள் இன்னும் கண்டிப்பாக இருக்கியமாகவே இருக்கும், மேலும் தரவின் விளக்கங்கள் வெளியிடப்படும்.

#### இந்த ஆய்வு வைதப் பற்றிக் கண்ட நித்தது?

வேலூர் மாவட்டத்தின் கிறிஸ்தல மருத்துலக் கல்லூடுமின் நிறுவன மதிப்பாப்வு வாடுயம் (IRB) இந்த ஆய்வு ஆய்வு செய்துள்ளது.

உங்கள் மருத்துவ தகலல் (தனிப்பட்ட விவரங்கள், உல் பரிசோதனை, விசாரணை மற்றும் மருத்துவ வரனறு) பற்றிய தனிபுரினம் தொடர்பாக நாங்கள் இரகசியத்திற்கு அரண உள்ளது. இந்த ஆவனத்தில் சைபெழுத்திடுவதன் மூலம், உங்கள் மருத்துவத் தகவலை அணுக வேண்டுமெனில் ஆராய்ச்சி குழு விசாரணையாளர்களை அனுமதிக்க வேண்டும்.

இந்த ஆராப்ச்சியின் ஒரு பகுதியாக நடத்தப்படும் மருத்துவ பரிசோதனைகள் மற்றும் சிகிச்சையின் முடிவுகள் ஊகள் மருத்துவ பதிவில் சேர்க்கப்படனம் விஞ்ஞான சஞ்சிகைகளில் வெளியிடப்பட்ட அல்லது விஞ்ஞானக் கூட்டங்களில் வழங்கப்பட்டிருந்தால், இந்த ஆய்வின் தகவல்கள் உங்கள் அடையானத்தை வெளிப்படுத்தாது.

இதை வாசிப்பதற்கு நன்றி.

# (iii) INFORMED CONSENT

Format for Informed Consen	nt Form for Subjects (English)
Informed Consent form to partici	pate in a research study
Study Title:	
Study Number:	
Subject's Initials:	
Date of Birth / Age:	
(Subject)	
(i)	I confirm that I have read and understood the
information sheet dated	for the above study and have had the
opportunity to ask questions. [ ]	

(ii)	I understand that my participation in the study is
voluntary and that I am free to wi	ithdraw at any time, without giving any reason,
without my medical care or legal i	rights being affected. [ ]
(iii)	I understand that the Sponsor of the clinical trial,
others working on the Sponsor's b	oehalf (delete as appropriate), the Ethics Committee
and the regulatory authorities will	l not need my permission to look at my health records
both in respect of the current stud	ly and any further research that may be conducted in
relation to it, even if I withdraw fr	rom the trial. I agree to this access. However, I
understand that my identity will n	not be revealed in any information released to third
parties or published. [ ]	
(iv)	I agree not to restrict the use of any data or results
that arise from this study provided	d such a use is only for scientific purpose(s). [ ]
(v)	I agree to take part in the above study. [ ]
(vi)	I am aware of the Audio-visual recording of the
Informed Consent. [ ]	
(Click here for Audio Visual guide	elines)
	•

# Date: \_\_\_\_/\_\_\_ Signatory's Name: **Signature:** Or Representative: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_ Signatory's Name: Signature of the Investigator: Date: \_\_\_\_/\_\_\_ Study Investigator's Name: \_\_\_\_\_ Signature or thumb impression of the Witness: Date: \_\_\_\_/\_\_\_ Name & Address of the Witness:

Signature (or Thumb impression) of the Subject/Legally Acceptable

# **Informed Consent - Tamil**

ஆய்வுக்கு நூக்கள் ஒப்புக் கொண்டால், இணைந்த ஒப்புதல் படிவத்தில் கைபொப்பிடுங்கள்.
தொடர்பு நபரை (முதன்மை விசாரணை)
டி.ஆர். திவியா கிடுதர்
பதவிடுவை: பி.டி.
கண் மநத்துவம் திணைக்களம்
கண் மநத்துவம், Schell கண் மநத்துவமனை,
СМС, Сажулії
தொலைபேசி எண்கள்: 9791296321
மின்னஞ்சல் ஐடி: divg1212@gmail.com
அனம்ச்சி அம்மில் மந்த நெரும்கள்
<b>படிப்பு தகைப்பு:</b> கிராமப்புற தென்னிந்திய வயதினர்களின் அடக்கமான தேவை மற்றும் செயல்பாட்டு நிலை ஆகியவற்றின் பிரசன்னம் <b>அருகில் உள்ள பாய்வை</b> (Presbyopia / near vision)- குறுக்கு வெட்டு ஆய்வு
ஆய்வு <del>என்.</del>
தலைபு தின் ஆரம்.ங்கள்:
பொருள் பெயர்:
பேற்க கேடி / வயது:
children ability is assessed to the control of the
(பொருள்) (நான்) மேற்கூறிய ஆய்வுக்காக தேதியிட்ட தகவல் தாள் படித்து புரிந்து கொண்டு, கேள்விகளைக் கேட்பதற்கான வாய்படைப் பெற்றுள்ளேன் என்பதை உறுதிய்.டுத்துகிறேன். []
(ஆ) இந்த ஆம்வில் பங்கேற்பது தன்னார்வாக இருப்தையும், வபோது வேண்டுமானாலும் என் மருத்துவ பராமிப்பு அல்லது சட்ட அிமைகள் பாதிக்கப்பாமல்,

(III)	நாள் மருத்துவ சோதனை வழங்குமார், ஸ்டாஸ்ஸ் சார்டாக வேலை மற்றவர்கள்
	( <b>மொதத்தமான நூக்க</b> ) என்.சைப் புரிந்துகொள்கிறேன் தெறி முறைகள் கமிட்டி மற்றும்
	ஒழுங்குபடுத்தும் அதிகார தற்போதைய ஆய்வு மற்றும் மேற்படியான மரியாதை இரண்டு என்
	ககாதார பதிவுகளை பார்க்க என் அனுமதி தேவைபில்லை விசாரணைபில் இருந்து நான்
	விலகி இருந்தாலும் கூட, அதைப் பற்றி ஆராயப்படக்கூடிய ஆராய்ச்சி. இந்த அணுகலை
	நான் ஏற்கிறேன். இருப்பினும், மூன்றாம் தரப்பினருக்கு வெளிபிடப்பட்ட எந்த
	தக்கல்களுடனும் வெளியிடப்படவோ வெளியிடவோ முடியாது என்பதை நான் புரிந்து
	செயல்கிறேன். [
(IV)	இத்ததைய படன்பாடு விஞ்ஞான நோக்கம் (கள்) மட்டுமே வழங்கப்பட்ட இந்த
	ஆம்வுகளிலிருந்து எழும் எந்திவாரு தரவு அல்லது முடிவுகளைப் பயன்படுத்துவதை நான்
	கட்டுப்படுத்துவதின்னை. []
(V)	மேலே உள்ள படிப்பில் பங்கேற்க நூன் ஒப்புக்கொள்கிறேன். []
(vi)	தகவல் அறியும் ஒப்புதலின் ஆடியோ காட்சிப்பதிவை நான் அறிந்திருக்கிறேன். []
1.4	(ஆடியோ விஷுவல் வழிகாட்டுதல்களுக்காக இங்கே கிளிக் செய்யவும்)
Quite	yai / சட்டபூர்வளக ஏற்றுச்சொள்ளப்பட்ட சைபொப்பர் (அல்லது கை முத்திரை)
du di	1 1
michica.	
ene Q	யாய்யிட் பெர்: கைபோட்டம்:
	444

அன்று

Qq&@&:
©⊕⊕://
oseQuminiti∟ Qumi:
ஆராப்ச்சியாளரின் கைபொப்பம்:
<b>(</b> 毎台:///////
ஆம்வு ஆராம்ச்சியாளரின் பெயர்:
சாட்சியின் சைபொப்பம் அல்லது கை எண்ணம்:
<b>C</b> ade://
சாட்சியின் பெயர் மற்றும் முகவரி:

## (ii) PROFORMA FOR DATA COLLECTION

## **SECTION A – GENERAL INFORMATION**

1.	NAME			2.	DATE OF EX	KAMINATIO	N
3.	STREET NAME						
4.	STREET NUMBER						
5.	HOUSEHOLD ID NUMBER						
6.	AGE	30-40 41-50 51-59 >60	years				
7.	SEX	MALE			FEMALE		
8.	EDUCATION						
9.	OCCUPATION						
10	. CO MORBIDITIES						

## **SECTION B – HISTORY AND EXAMINATION**

1. Are you currently using spectacle	es? Yes No
Yes	No
2.Reason for use- Near vision/ Distance vision/ protection/ fashion	2. If no, have you used in the past? Yes No
3Did you have an eye check-up when you got your glasses? Yes No	<ul><li>3. Do you have a problem with your vision?</li><li>Yes  No</li></ul>
4. Where did you get them from?	<ul><li>4. Did you ever have an eye check-up?</li><li>Yes □ No□</li></ul>
Hospital eye unit /Local health care centre/Optical shop/Second hand shop/Peripheral camps/Don't know my family member bought it for me/I use another family members glass	
5. Are you happy with your vision with these glasses? Yes No No	5. Were you ever prescribed spectacles? Yes No
6.If not ,mention reason for using for specs with poor vision	6. Mention barrier for spectacle use / eye check up
Cost/Not felt the need/Poor availability /No time	Cost/Not felt the need/Poor availability/ Cosmesis / Broken/scratches/Not accepted in community

# **EXAMINATION**

	RIGHT	LEFT
UNAIDED VISION		
PINHOLE VISION		
PRESENTING VISION (WITH PG)		

RIGHT EYE	LEFT EYE
	RIGHT EYE

EXAMINATION	RIGHT EYE	LEFT EYE
MOTILITY		
ROPLAS		
CONJUNCTIVA		
CORNEA		
AC DEPTH		
RAPD		
IOP		
LENS DIAGNOSIS		
FUNDUS		

### **SECTION C**

## **CAUSE FOR DECREASED VISION**

RIGHT EYE LEFT EYE

- 1. REFRACTIVE ERROR
- 2. PRESBYOPIA
- 3. CATARACT
- 4. PSEUDOPHAKIA
- 5. GLAUCOMA
- 6. APHAKIA
- 7. CORNEAL SCAR
- 8. POSTERIOR SEGMENT PATHOLOGY
- 9. OTHERS

## TREATMENT PLAN

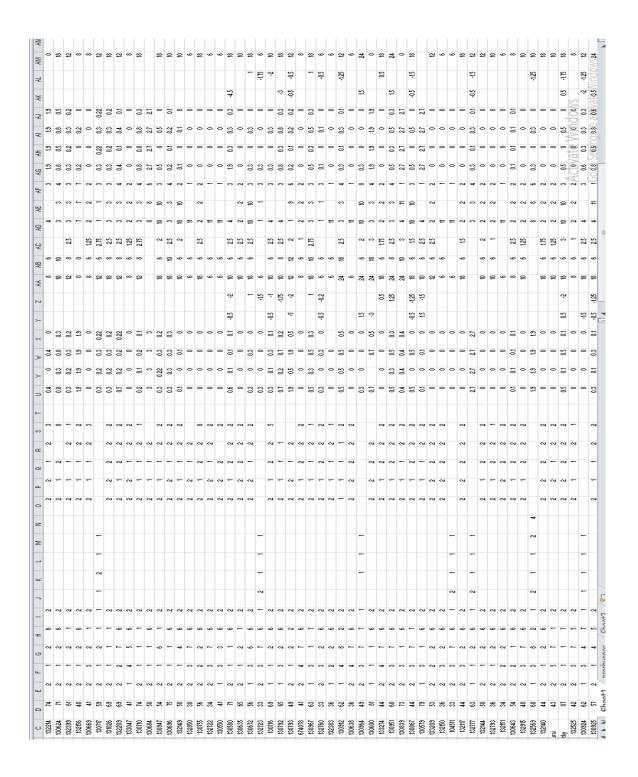
- 1. Nil
- 2. Presbyopic glasses
- 3. Spectacles
- 4. Cataract Surgery
- 5. Glaucoma work up
- 6. Evaluation
- 7. Others

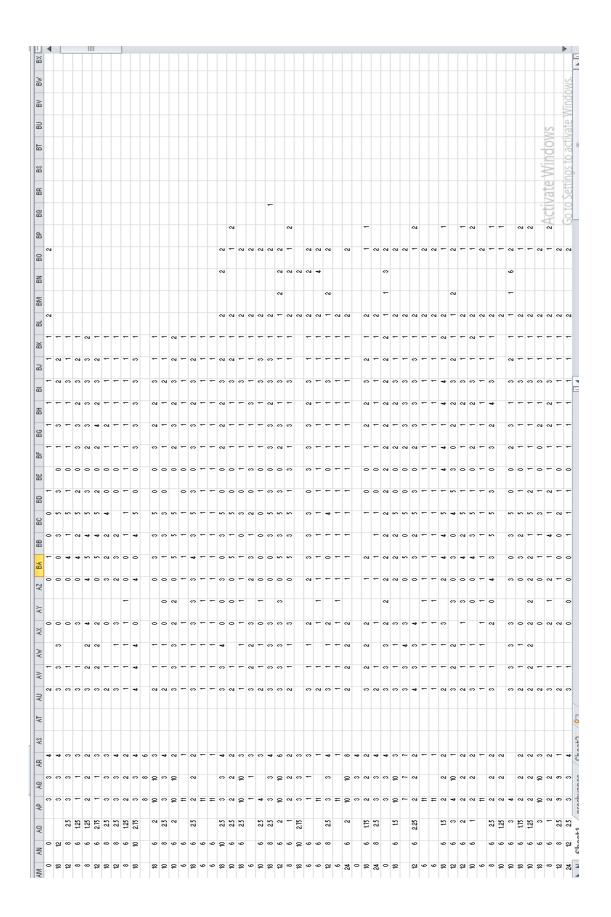
# **QUESTIONNAIRE**

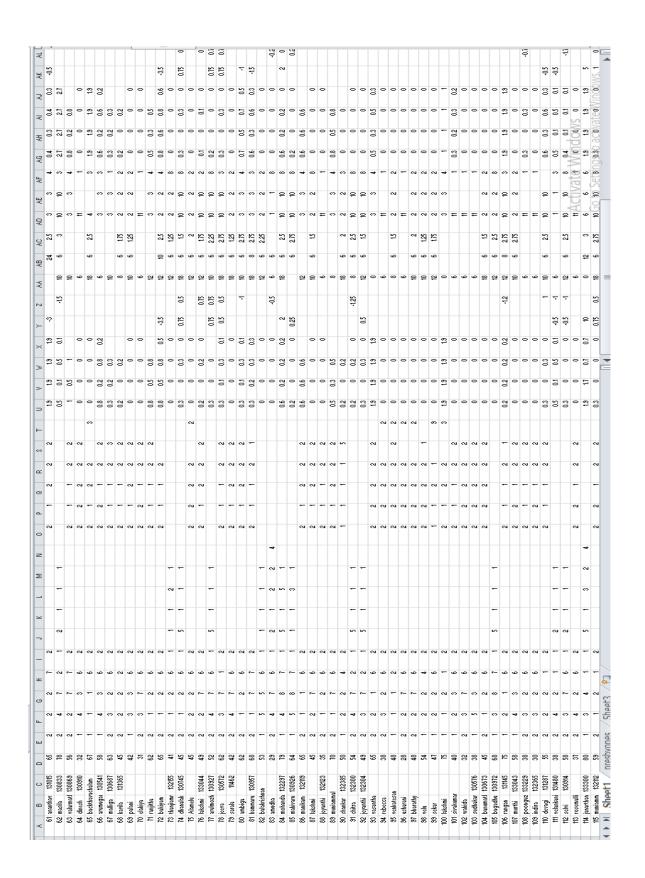
HOW IS YOUR VISION IN BOTH EYES?	1	VERY GOOD	GOOD	MODERATE	BAD	VERY BAD
HOW MUCH DIFFICULTY DO YOU HAVE IN PERFORMING DAILY ACTIVITIES?	(	NONE	MILD	MODERATE	SEVERE	CANNOT DO
IF YES ,HOW MUCH OF THE ABOVE DIFFICULTY IS DUE TO NEAR VISION		NONE	MILD	MODERATE	SEVERE	CANNOT DO
	Activity done or not?					
HOW MUCH DIFFICULTY DO YOU HAVE DOING THESE ACTIVITIES?		NONE	MILD	MODERATE	SEVERE	CANNOT DO
<ol> <li>READING,         WRITING         (includes signing of accounts,         ATM use, bank account)</li> </ol>	g					
2. USING MOBILE PHONE						
3. CLEANING HAIR OF CHILDREN						
4. COOKING (including cutting vegetables, seeing the grain while cleaning)	ıs					
5. THREADING NEEDLE						

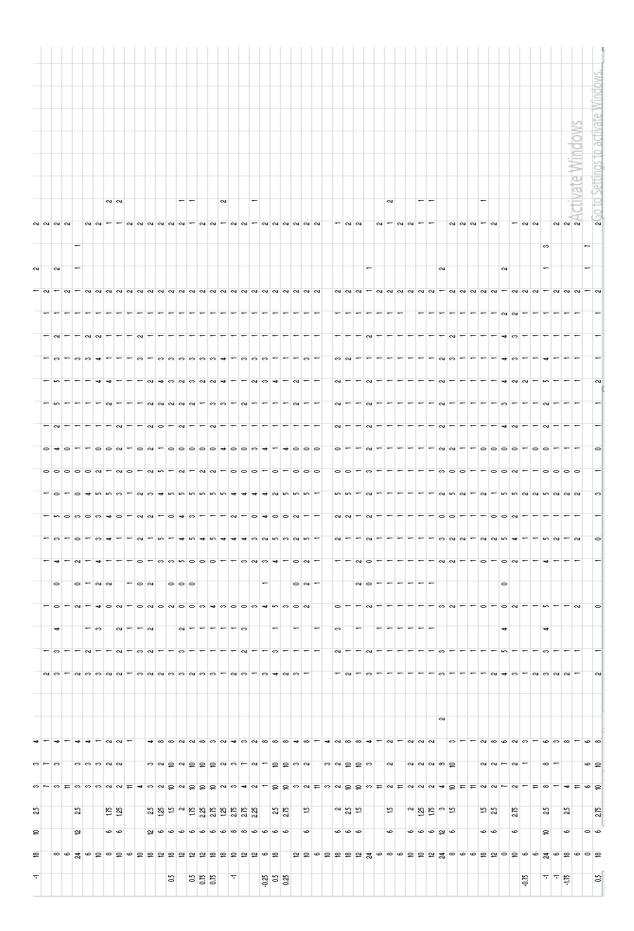
6. HARVESTING			
7. TO TEACH			
CHILDREN AT			
HOME( to help			
with homework)			
8. SEEING LEVEL IN			
A CONTAINER			
WHILE			
POURING?			
9. UNLOCKING A			
DOOR WITH A			
KEY?			
10. SEEING OBJECTS			
IN YOUR FOOD?			
(while eating)			
(writte eating)			

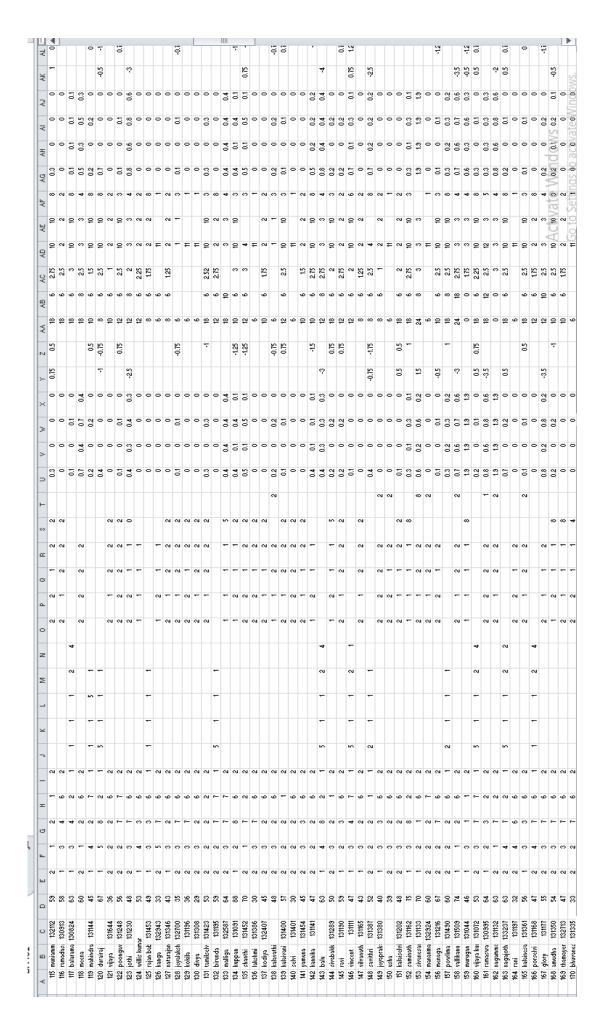
#### (v) DATA ENTRY

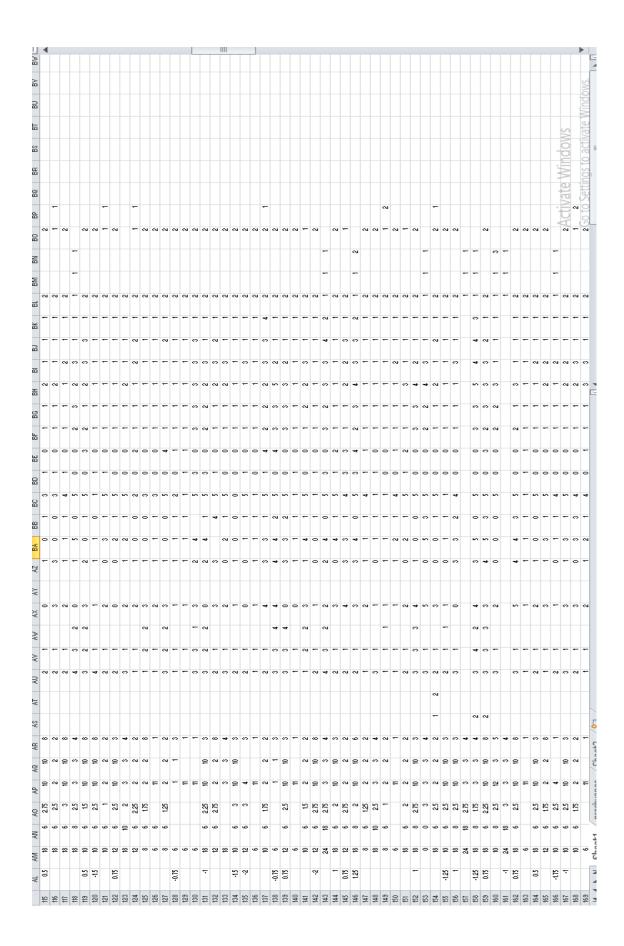


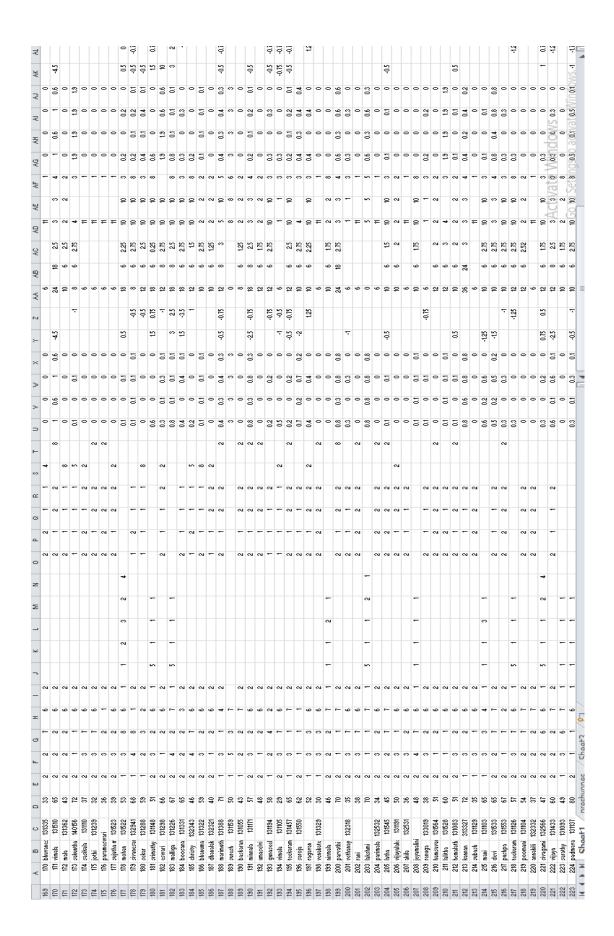


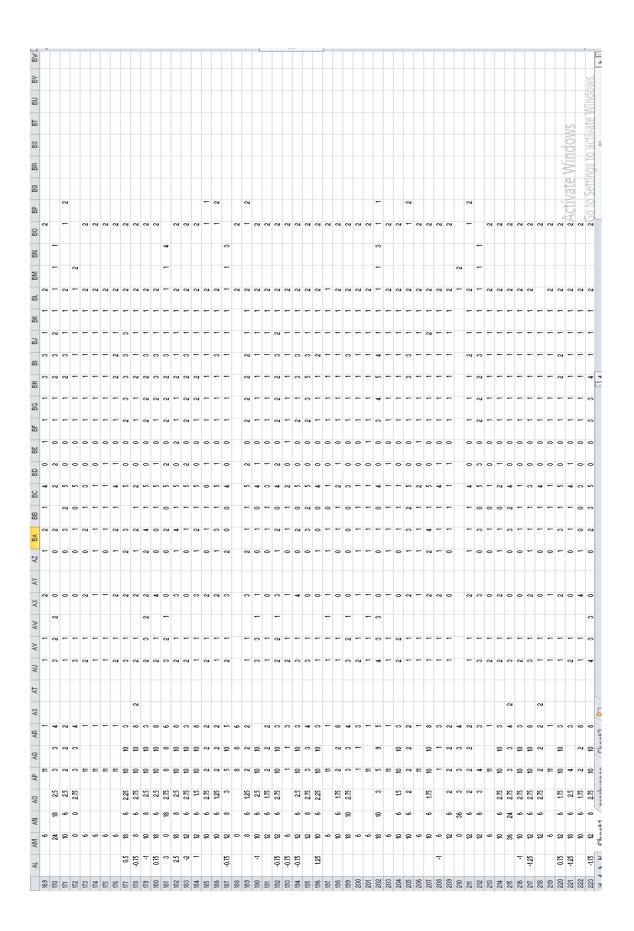


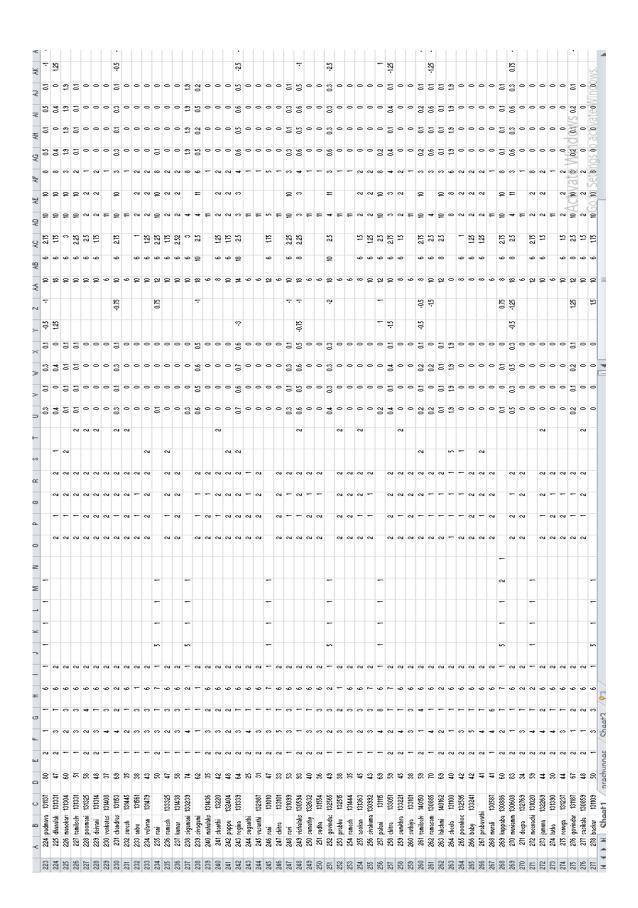


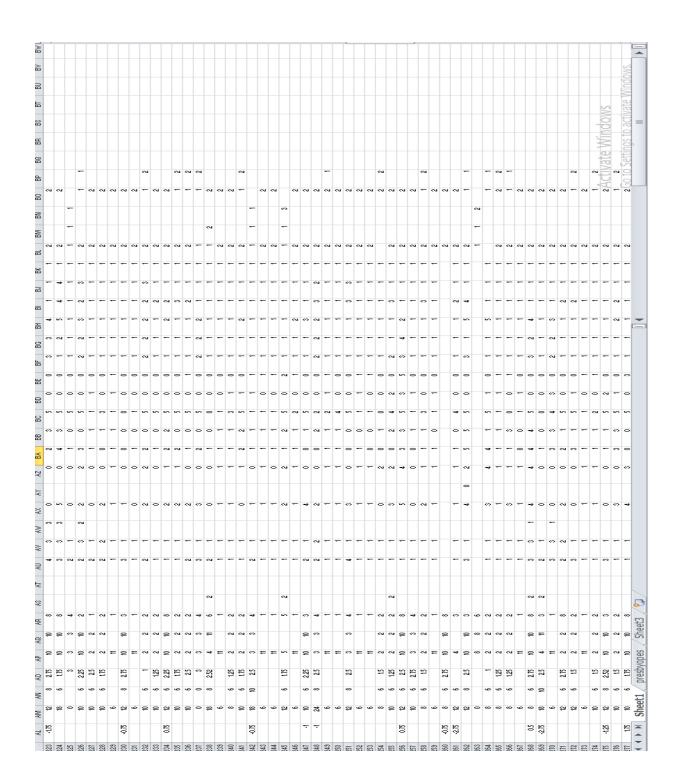




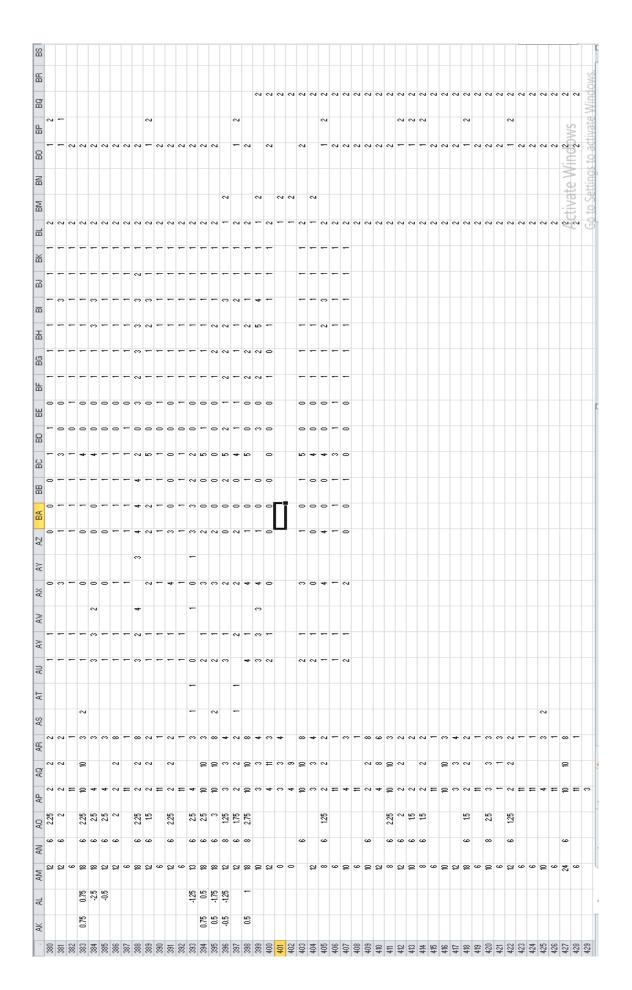








Windley (2006)         50 2 2 1 7 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	382 mohan 13	130807 57	-		7	4	2				_	_	,	,					=						,			٠
	<b>P</b>		- 0	, ~	-	) r-	, ~	-	-		10	a -	1 0	, ~	ŀ		•	• =	, c		ŀ			, ~	1 0	۰ د		
	chitra		2	1 -3-	r~	. 60	1 2	-			2	- 2	2	1 ~	L									· =				9
00000 14 1 1 1 2 2 2 1 1 1 1 2 2 2 1 1 1 1 1	erojohn 1		2	7	r~-	-	2				2	-	-	~			-	07	0					=	2			0
100   100	thanian		-	-	-	7	7				7	7	7	7			0	0.5	0					4				동
Digital State   Color   Digital State   Digi	govinda		2	-	r~	9	+	-	_	-						8	8	3	8	÷ 5				~	~			0
THE STATE OF THE S	eks		7	en	~	9	-	+	_	_		+	-	-	_		0	0	0	+	-			7	7			0
10.000	gonindai		2	2	2	9	2				2	7	2	2			0	0	0					=				0
10000000000000000000000000000000000000	sumathi		2	က	r~	9	-	-	_	_							0	0	0					7	~			0
00000 000 000 000 000 000 000 000 000	manjula		7	က	-	9	7				2	7	7	2			0	0	0					7	7			0
10   10   10   10   10   10   10   10	efiudefie		7	က	~	9	7				2	7	7	7			0	0	0					=				$\circ$
Column   C	ramesh		-	က	2	9	7				2	-	7	7			-	0	0		_			7	7			$\circ$
1	shabnu		2	en	r~	9	7				2	2	7	~			0	0	0					=				0
1	shakirab		2	7	~	9	7				7	2	7	2			8	0.5	8					-				$\Xi$
Marco   Marc	돌		-	-	2	9	~				2	-	2	~	e	13	0	8	0					0	9			0
Mark			-	7	-	~	-	LO.	-	-						9:0	8	8	53					0	9			$\equiv$
Mark			2	en	r~	9	2				2	-	2	~			83	90	03					es	en			22
Mark   St. 1   4   St. 6   1   5   1   1   1   1   1   1   1   1	ravichan		-	en	en	9	2				2	-	2	~			0	0	0					~	7			0
Marker   Secondary   Seconda	400 kamaraj	83	-	-	00	9	-	ю	-	_						0.2	8	07	10	-0.5				9	9			2
11   1   1   1   2   2   2   2   2   2			-	က	4	9	2				-	-	2	-	es	52	ಐ	52	22					e	en			23
Fig. 18   1   1   1   1   1   1   1   1   1	saminat		-	-	-	4	7				-	7	-	-		8	90	88			.7			-	=			23
Fig. 18   1   1   2   2   2   2   2   2   2   2	yeshoda		2	en	r~	9	7				2	-	2	~			90	88						~	က			93
10   10   10   10   10   10   10   10	yeshoda		2	-	r~	2	~				2	-	-	~		2.7	27	2.7				_		~	က			93
10,000,000,000,000,000,000,000,000,000,	loganath		-	7	-	9	-	ß.	_	-						8	0	0	0					0	2			0
1   2   2   2   2   2   2   2   2   2	Saroja		2	-	r~	~	~				~	7	2	~	~	8	83	88						~	en			23
10   10   10   10   10   10   10   10	padman		-	en	en	2	~				-	7	-	-			0	0	0					~	~			0
1	varalaks		2	en	~	9	~				~	7	2	~			0	0	0					=				0
150072   28   2   5   7   6   2   7   7   6   2   7   7   7   7   7   7   7   7   7			2	7	LO.	~	7				2	-	-	7			0	0	0		-			<b>-</b>				21
1	eMip		2	ю	r~-	9	7				7	7	7	7			0	0	0					=				0
15   1   2   2   2   2   2   2   2   2   2	шенада		2	-	-	9	2				-	2	-	-	2	0	0	0	0					7	7			0
19   12   2   2   2   2   2   1   2   2	paranjot		2	-	r~-	-	7				7	-	-	~		8	98	8			. 4			-				99
13   1   2   2   6   7   7   7   7   7   7   7   7   7	venda		2	~	7	2			-	4		+				0.2	0	05	+	+				0	2			0
15   2   2   2   6   15   15   15   15   15   15   15	palanive		-	~	2	9										0	-	0	+					~	7			0
1   1   2   3   7   6   1   1   1   1   1   1   1   1   1			2	~	2	9	+	+				+	+	+		0	-	0	+	-				~	7			0
38         1         3         3         6         11         1         0			21	en .	~	9	+		+		1	+	+	+	4	0	-	۰.	+	+				~	~			0
Parameter   Para	417 ravindran	88 1	-	· ·	· ·	ω.	+	+	+	-	1	+	+	+	+	٥:	= :	٥:	+	+				=				- I
Positive and state of the control of the co	478 amudha	8 !	7	-	7	۰ م	+	+	+	-	1	+	+	+	+	e:	77 :	3:	+	+	-			≥ .	≥ .			2919
Parish   P	413 padma	Ç !	7	7	7	. م	+	+	+	-	1	+	+	+	+	90	e .	æ .	+	+	-			· ·	· co			دا⊵
Probath   38   1   3   3   6   1   9   9   9   9   9   9   9   9   9	#50 nalini	<b>?</b> :	7		٠,	، ص	+	+	+	-		+	+	+	-	9 '	٠,	٠.	>	+				~ :	7			- I
Sector         62         3         1         6         1         5         3         3         3         3         3         3         3         3         3         3         3         3         3         3         3         3         4         3         3         4         3         1         1         0 </td <td>421 prabath</td> <td>8 8</td> <td>-</td> <td>~ 0</td> <td></td> <td>0</td> <td>+</td> <td>-</td> <td>+</td> <td>1</td> <td><math>\dagger</math></td> <td>+</td> <td>+</td> <td>+</td> <td>-</td> <td>9 8</td> <td>&gt; 4</td> <td>&gt; 8</td> <td></td> <td>+</td> <td>-</td> <td></td> <td></td> <td>= &lt;</td> <td>•</td> <td></td> <td></td> <td>⊃   b</td>	421 prabath	8 8	-	~ 0		0	+	-	+	1	$\dagger$	+	+	+	-	9 8	> 4	> 8		+	-			= <	•			⊃   b
Septemblishment   Section   Companies	FZZ SeKal	70 :	-		-	۰.	+	+	+	1	1	+	+	+	-	8 :	e ·	200	+		1							양년
43         1         3         3         6         120         2         3         1         3         3         4         3         3         5           And analysismin and analysismin and analysismin and analysismin and analysismin and analysismin analysismin and analysismin analys	423 Komathi	١.	.7	~ 0	000	ъ «			+	+	+	+			+	200	5 0	200	•		+							0 0
Programmal         36         1         3         3         6         11         1         0 <t< td=""><td>524 Sentmikuma</td><td>+</td><td>-</td><td>20</td><td>200</td><td>0 0</td><td>+</td><td>+</td><td>+</td><td>1</td><td>†</td><td><math>\dagger</math></td><td>+</td><td>+</td><td>+</td><td>&gt; &lt;</td><td>&gt; &lt;</td><td>&gt; &lt;</td><td>&gt; &lt;</td><td>+</td><td>1</td><td></td><td></td><td>7 3</td><td>7</td><td></td><td></td><td>2 0</td></t<>	524 Sentmikuma	+	-	20	200	0 0	+	+	+	1	†	$\dagger$	+	+	+	> <	> <	> <	> <	+	1			7 3	7			2 0
Verkidesan         43         1         3         3         6         III         1         0           Adatanimal         60         2         1         1         1         1         3         0.5           Adatasamili         30         2         5         5         6         11         1         0           Adatasamili         48         2         3         6         1         1         0           Adatasamili         38         1         3         5         6         1         1         0         0         0         0         6         Activate Windows 1         0         1         0	25 pragalaman	+	-	~	~	۰ م	+	+	+	1	$\dagger$	+	+	+	+	٥,	-	> <	-	+	+			= 3	+			$\rightarrow$
kanamal 60 2 1 1 1 1 8 4 3 05 05 05 05 05 18 4 3 05 05 05 05 05 05 05 05 05 05 05 05 05	26 venkatesan	Ç2		m	m	9	+	-				+	-	-		0	0	0	+	1				=		-		0
abitami         30         2         5         3         6         11         0	27 kanammal	8	2	+	-	-	+	1						+		0.5	8	9	1	1	-			-		~		21
1 0.2 24 Setivate Windows 8 1 3 3 6 8 4 Hindows 1 1 0.2 24 Setivate Windows 1 1 0.2 24	428 abirami		7	LO.	en	9	+	+	4	_	1	+	+	+	4	0	-	-	+	+	4			=				0
1 3 8 1 3 8 1 3 8 E	429 ramalkshmi	+	7	en	7	9	+	+	4	_	1	+	+	+	_			0.5	+	+			4	100			_	
	120 nalathamahi		-	~	~	4												<					3 / 3 / 3		2			=



## At the study clinic

## 1. Registration



### 2. Vision and ocular examination



## 3. Administration of questionnaire



## **Door to door visits**

## Vision assessment



### Ocular examination

