

**THE VISION-RELATED QUALITY OF LIFE USING
NEI-RQL-42 AND ITS ASSOCIATED FACTORS IN
UNDERGRADUATE STUDENTS WITH MYOPIA**

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DISCLAIMER

I hereby certify that the work in this dissertation is my own except for the quotations and summaries which have been duly acknowledged.

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Abbreviations

NES II	National Eye Survey II
SE	spherical equivalence
D	dioptries
MMD	myopic macular degeneration
WHO	World Health Organization
USD	United States dollars
LASIK	laser-assisted in situ keratomileusis
VRQOL	Vision-related quality of life
NEI	National Eye Institute
RQL	Refractive error Quality of Life
NEI-RQL-42	National Eye Institute-Refractive error Quality of Life-42
RSVP	Refractive Status and Vision Profile
CLIQ	Contact Lens Impact on Quality of Life
VFQ	Visual Functioning Questionnaire
ED-5D	European Quality of Life-5 Dimensions
NEIVFQ-25	25-Item National Eye Institute Visual Functioning Questionnaire
USM	Universiti Sains Malaysia
UiTM	Universiti Teknologi MARA Kelantan
UMK	Universiti Malaysia Kelantan
SPSS	Statistical Package for Social Sciences
SD	standard deviation
IQR	interquartile range
IT & CS	information technology and computer science

B40	Bottom 40%
DOSM	Department of Statistics'
HIS/ BA	Household Income and Basic Amenities
M40	Middle 40%
T20	Top 20%
VF-14	Visual Function-14
OK	Orthokeratology
QIRC	Quality of Life Impact of Refractive Correction
PREP	Pediatric Refractive Error Profile
CDC	Centers for Disease Control and Prevention
SF-36	36-item short-form health survey
NA	Not available
CVS	computer vision syndrome
COVID-19	coronavirus disease of 2019

Abstrak

Pengenalan

Kadar kelaziman miopia atau rabun jauh dalam populasi dunia terutamanya Asia semakin meningkat. Walau bagaimanapun, terdapat kekurangan penyelidikan berkenaan kualiti kehidupan berkaitan dengan penglihatan (VRQOL) dijalankan di kalangan orang ramai yang menghadapi masalah rabun jauh.

Objektif

Untuk menilai kualiti kehidupan berkenaan dengan penglihatan serta faktor-faktor berkaitan dengan borang soal selidik NEI-RQL-42 di kalangan pelajar-pelajar sarjana yang menghadapi rabun jauh.

Methodologi

Kajian telah dijalankan secara keratan rentas (cross-sectional) di universiti-universiti berada di Kelantan yang terpilih dari December 2018 hingga November 2020. Sampel-sampel kajian dipilihkan dengan kaedah persampelan mudah bertujuan di mana sampel-sampel yang sesuai akan dipilihkan selepas pengambilan sejarah berkaitan, saringan penglihatan dan pemeriksaan mata serta ujian refraksi. Sampel-sampel yang terpilih akan diminta untuk menjawab borang soal selidik NEI-RQL-42.

Keputusan

Seramai 458 orang berumur daripada 18 hingga 29 tahun telah menyertai kajian penyelidikan kami (378 orang menghidapi rabun jauh dan 80 orang yang bebas daripada rabun mata (emmetrope)). VRQOL responden yang menghidapi rabun jauh (62.20 ± 9.53) adalah kurang baik jika berbanding dengan responden emmetrope (81.12 ± 12.72) secara ketara dalam min skor global ($p < 0.001$). Pada masa yang sama, responden emmetrope mencapai markah lebih tinggi dalam semua subskala secara ketara ($p < 0.05$) kecuali domain symptom ($p = 0.319$). Pengguna-pengguna kanta lekap mencapai min skor global (58.68 ± 8.16) yang lebih rendah secara ketara ($p < 0.050$) jika dibandingkan dengan pengguna-pengguna cermin mata. Selepas pelarasan faktor-faktor kekeliruan, pelajar-pelajar sarjana aliran berunsur kesihatan mencapai min skor global lebih rendah secara ketara daripada pelajar-pelajar sarjana aliran lain.

Kesimpulan

Pelajar-pelajar sarjana yang menghidapi rabun jauh mencapai purata markah NEI-RQL-42 yang lebih rendah secara ketara daripada golongan emmetrope. Pengguna-pengguna kanta lekap mencapai purata markah VRQOL yang lebih rendah secara signifikan jika dibandingkan dengan pelajar-pelajar yang bercermin mata. Pelajar-pelajar sarjana aliran berunsur kesihatan dapat menjejaskan VRQOL secara signifikan.

Abstract

Introduction

The prevalence of myopia is getting higher around the world especially in Asia. However, there is limited study regarding the vision-related quality of life (VRQOL) among the myopes.

Objective

To evaluate the vision-related quality of life using (National Eye Institute-Refractive Error Quality of Life Instrument-42) NEI-RQL-42 and its associated factors among undergraduate students with myopia.

Methodology

A cross-sectional study was conducted in selected universities in Kelantan from December 2018 till November 2020. The samples were selected with the convenience purposive sampling method. The participants were recruited after the relevant history taking, ocular screening, and refraction. The suitable subjects were asked to answer the NEI-RQL-42 questionnaire.

Result

A total of 458 participants aged 18 - 29 years were recruited (378 were myopic and 80 were emmetropic). Myopes had poorer VRQOL significantly ($P < 0.001$) in mean global score (62.20 ± 9.53) than emmetropes (81.12 ± 12.72) and showed a lower score in all subscale scores significantly ($P < 0.05$) except symptoms domain ($P = 0.319$). Contact lenses wearers reported significantly poorer VRQOL with a lower mean global score (58.68 ± 8.16 ; $p = 0.001$) comparing to spectacles wearers. After adjustment for other confounding factors, health-related courses were significantly more likely to report poorer global scores of VRQOL than other courses.

Conclusion

There was a significant difference in the mean score of NEI-RQL-42 between myopes and emmetropes in which myopes had poorer VRQOL. Contact lenses wearers acquired a significantly poorer mean score statistically compared to spectacles wearers. Health-related courses can cause a poorer mean score of VRQOL significantly.

Chapter 1

Introduction

1.1 REFRACTIVE ERROR

Refractive error occurs when the parallel rays of light entering the non-accommodating eye fail to focus directly on the retina and leads to a blurred image. Myopia is defined as when parallel light rays from a distant image are focused on a point in front of the retina. On the other hand, hyperopia is defined when the distant parallel light rays are focused behind the retina. Astigmatism occurs when the light rays do not converge at a single focal point. Presbyopia is not truly a refractive error and it is resulted from insufficient accommodation for near work while distance refractive error is fully corrected (Chuck *et al.*, 2018).

Uncorrected refractive error (43%) is the principal cause of vision impairment globally, followed by cataract (33%), especially in Asia (Hashemi *et al.*, 2018; Hsieh & Lin, 2016). It is also the leading cause of blindness after cataract as reported in the Global Burden of Disease study (20.9% and 33.5% blindness, respectively) (Kadel *et al.*, 2018). National Eye Survey 1996 also reported uncorrected refractive errors were the major cause of low vision (48%), followed by cataracts (35.93%).

Visual impairment secondary to uncorrected refractive errors appeared to have two peaks prevalence by age, among young adults and older people (Zainal *et al.*, 2002). On the other hand, the National Eye Survey II (NES II) which conducted among the residents aged 50 and above in Malaysia also showed uncorrected refractive error (14.4%) was the second most common cause of moderate and severe visual impairment, while the most common cause was untreated cataract (68%) (Chew *et al.*, 2018).

Uncorrected refractive error contributed to an estimated 700 million cases of vision impairment worldwide in 2007 (Mahayana *et al.*, 2017). Given refractive error was a major cause of preventable visual impairment, so it became an important health issue in Malaysia especially among Malaysian children with its prevalence ranged 5.8 - 33.3% (Farhana *et al.*, 2012).

1.1.1 Myopia and its classification

Myopia is a spherical refractive error secondary to excessive refractive power and/ or axial elongation of the globe causing focus displaced anteriorly to the retina and lead to a blurred image.

In general, most recent epidemiological studies reporting prevalence rates of myopia defined myopia as spherical equivalence (SE) ≤ -0.5 dioptries (D) in either eye while various definitions been used with a range of SE ≤ -0.12 D to SE ≤ -1.0 D (Foster & Jiang, 2014; Holden *et al.*, 2016). Guo *et al.* (2016) further classified the myopia as low myopia (≤ -0.5 to > -3.0 D), moderate myopia (≤ -3.0 to > -6.0 D), and high myopia (≤ -6.0 D) based on the SE.

There are varies of the definition used to define high myopia by studies includes < -5.00 D myopia, ≤ -5.00 D, < -6.00 D myopia, ≤ -6.00 D myopia and ≤ -8.00 D myopia. Nevertheless, the participants of the Joint World Health Organization-Brien Holden Vision Institute Global Scientific Meeting on Myopia agreed that the best definition of high myopia as SE ≤ -5.00 D in view of a person who has -5.00 D uncorrected myopia has a visual acuity of 6/172, which is much worse than the threshold for blindness ($< 3/60$ in the better eye) (Ang & Wong, 2020; WHO, 2015; Wu *et al.*, 2016). In summary, we can classify myopia as shown in Table 1.1.

Table 1.1 Classification of myopia

Grade of myopia	Spherical equivalence (dioptries)
Low	≤ 0.5 to > -3.0
Moderate	≤ -3.0 to > -5.0
High	≤ -5.0

Myopia also can be defined when the axial length is greater than 24mm while axial length greater than 26mm is defined as high myopia. However, axial length may not an accurate criterion as it can be a normal variant and the overall eye power is derived from a combination of the lens, cornea, and axial length. Thus, some eyes with longer or shorter axial lengths have no refractive error. Moreover, the measurements can be affected by using different instruments (WHO 2015, Wu *et al.*, 2016).

On the other hand, high myopia can lead to myopic macular degeneration (MMD) which commonly causes vision impairment. MMD is clinically defined as myopic people with diffuse, patchy macular atrophy with or without lacquer cracks, choroidal neovascularization, and Fuchs spot. (WHO, 2015).

1.1.2 Prevalence of myopia of the world

In 2010, there were approximately 27% (1893 million) with the myopia of the world population and 2.8% (170 million) with high myopia. The highest prevalence of myopia was in east Asia where China, Japan, the Republic of Korea, and Singapore with a prevalence of approximately 50%. On the other hand, the prevalence of myopia was lower in Australia, Europe, and north and south America.

By 2050, the prevalence of the global population is predicted to increase to 52% (4949 million) for myopia and 10.0% (925 million) for high myopia. At the same time, the prevalence of myopia is expected to be higher in high-income regions of the Asia-Pacific such as east Asia and south-east Asia.

Similarly, the prevalence in high-income North America, southern Latin America, all of Europe, North Africa, the Middle East, and about 30% of Africa will have the same increasing trend as in Asia today. The prevalence of high myopia in all the Global Burden of Disease regions and high-income Asia-Pacific countries is estimated to 24% (WHO, 2015).

Hashim *et al.* (2008) stated that the prevalence of refractive errors among children varies widely such as less than 1% in rural Tanzania, 8.1% in Katmandu, 14.8% in Malaysia, 36.7% in Hong Kong, and more than 50% in Singapore. In their study, they found that myopia was the most common refractive error (77.5%), with a prevalence rate of 5.4% which was strongly related to demographic and social factors such as

time spent on reading books, larger housing types, increased family incomes, higher educational levels of parents and family history of refractive errors.

Recently, Ding *et al.* (2017) summarized the prevalence rates of myopia and its risk factors in East Asian and Singaporean school children, and they showed the prevalence of myopia was gradually increasing in trend. From the literature reviews, the prevalence of myopia is closely related with the age.

In Taiwan, Lin *et al.* (2006) reported the prevalence of myopia in the 16- to 18-year-old age group was 85.1%. In South Korea, Jung *et al.* (2012) reported the prevalence of myopia was 96.54% while Lee *et al.* (2013) reported 83.3% for those 19-year-old age group. In Singapore, Quek *et al.* (2004) reported the prevalence of myopia for the 15- to 19-year-old group was 74.2% among the Chinese population and 69.4% among the Malay population (Ding *et al.*, 2017).

Another systemic review and meta-analysis by Dong *et al.* (2020) found that the prevalence of myopia in the 16- to 18-years olds was kept increasing in trend which was 84.8% that be demonstrated by studies performed after 2013. Their result showed comparable results with the prevalence of myopia in Singapore's high school students aged 15 years to 19 years which was 73.9%. Zhang & Deng (2020) also stated that myopia prevalence among university students in central China was 83.2%. These literature reviews reflected that the prevalence of myopia is high among undergraduate students with their common age around 18 up to 24 years old.

1.1.3 Implications of myopia

108 million people globally are estimated to have uncorrected distance refractive error in 2013 which is the leading cause of moderate and severe vision impairment (42%). Uncorrected myopia of -1.50D can cause moderate vision impairment while uncorrected myopia of -4.00 may lead to blindness. As there is a prediction of a 2.6-fold increase in the global prevalence of myopia, thus, a similar increase in uncorrected refractive error is expected (WHO, 2015).

Fricke *et al.* (2012) reported that the annual cost of the productivity lost due to refractive visual impairment globally was estimated to cost 269000 million international dollars, equivalent to 202000 million United States dollars (USD).

In urban areas of Asia, 80-90% of young adults are myopic and 10-20% have high myopia. Thus, the estimated annual direct cost of myopia correction for Asian adults is 328 billion USD/ annum and the cost of care is likely increasing significantly because the prevalence of myopia is in increasing trend (Ang & Wong, 2020).

In Singapore with a high prevalence of myopia, the eye examination and optical devices for vision correction cost about 148 USD/child/annum while the additional costs for the laser-assisted in situ keratomileusis (LASIK) in adults was 709 USD/adult/annum. Comparably, the economic costs associated with myopia were estimated to be USD 4.6 billion/year which were relatively high among adults in the United States (Zhang & Deng, 2020).

Myopia is not only causing a big impact financially, but it can cause secondary impact from other eye diseases and vision loss including cataracts, glaucoma, retinal detachment, and MMD. Subsequently, these visual impairments will lead to more cost burdens. The visual impairment will affect the quality of life as it may limit the activities involving mobility, daily living, and visually intensive tasks. At the same time, it also may impact education, employment, child development, mental health, and functional capacity in older people (Ang & Wong, 2020; Holden *et al.*, 2016).

Similar implications of myopia were described by Holguin *et al.* (2006) in which myopia at all levels results in blurred far vision. This subsequently significantly affects academic performance and reduced scholastic and social participation. Khandekar *et al.* (2013) stated that myopia with spectacles correction had a distinctive impact on vision-related quality of life (VRQOL) associated with the worry of injuries and management of daily activities.

1.2 VISION-RELATED QUALITY OF LIFE

The primary considerations for evaluation of the vision status of the patients mainly only concentrated on the measurement of the refractive status clinically, uncorrected, and best-corrected visual acuity traditionally, but did not consider the patient-based subjective assessment of outcomes.

The National Eye Institute recognized the need to “...study quality of life and functional status as perceived by the patient...to assess the full impact of a treatment or disease process.” This is because research on cataract surgery showed that patient-reported assessments of functioning, satisfaction, and symptoms capture aspects not detected by the traditional clinical measure of the need for and outcomes of surgery.

Thus, several questionnaires were developed thereafter to evaluate the symptoms, baseline functioning, and perception for those people who wish for refractive surgery. At the same time, it allows a comparison of the impact of treatments on social and psychological functions. Moreover, health-related quality-of-life surveys can be used to discriminate between two groups at a single point in time, to predict future outcomes, or to measure changes over time (Vitale *et al.*, 2000; Walline *et al.*, 2000).

The National Eye Institute (NEI) created the 42-item Refractive Error Quality of Life (RQL) questionnaire for the specific assessment of the subjective visual and functional effects of refractive error and its correction, either with contact lenses, eyeglasses, or surgery. Lin *et al.* (2010) claimed that the NEI RQL instrument is sensitive enough to detect the visual benefit of cataract surgery.

Similarly, McDonnell *et al.* (2003) and Pakpour *et al.* (2013) stated that the National Eye Institute – Refractive error Quality of Life – 42 (NEI-RQL-42) is a valid and reliable instrument to assess refractive error correction of quality of life and can be used to evaluate the effectiveness of interventions in patients with refractive errors.

On the other hand, Shams *et al.* (2015) compared the quality of life between myopic patients with spectacles and contact lens, and patients who have undergone refractive surgery with NEI-RQL-42. They found that the quality of life for people with myopia who had refractive surgery was better than people with myopia who wore spectacles or contact lens. This showed that refractive surgery can improve the quality of life of myopic people although it was less than emmetropia.

Queiros *et al.* (2012) evaluated the VRQOL in low and moderate subjects corrected with different refractive treatments by using NEI-RQL-42. They concluded that LASIK had the lowest average decrease in quality of vision compared with emmetropes.

Vitale *et al.* (2000) described that the Refractive Status and Vision Profile (RSVP) is a valid questionnaire as measured by accepted standards for psychometric instruments and reliable for use in studies to evaluate devices and procedures for correction of refractive error. Pesudovs *et al.* (2004) developed and validated a questionnaire (The Contact Lens Impact on Quality of Life (CLIQ) Questionnaire) for the measurement of the impact of contact lenses on quality of life.

Other validated questionnaires have been used in researches including the Visual Functioning Questionnaire (VFQ)-25 and the European Quality of Life-5 Dimensions (EQ-5D) to assess the quality of life (Lin & Yu, 2012).

Hays *et al.* (2003) reported that NEI-VFQ-25 is a reliable and validated instrument to compare people with different types of correction for refractive error. However, Walline *et al.* (2000) mentioned that the NEI-VFQ is not appropriate for detecting significant differences in VRQOL among spectacle, soft contact lens, and rigid gas-permeable contact lens wearers, primarily due to maximum ratings by many of the subjects. On the other hand, Mangione *et al.* (2001) concluded that NEIVFQ-25 which is a shorter version of 51-item NEI-VFQ is more feasible in clinical trials where interview length is a critical consideration and can provide reproducible and valid data when used across multiple conditions of varying severity.

Hsieh *et al.* (2016) revealed myopes were associated with difficulties in near and distance vision compared to emmetropes among the junior high school students in Taiwan by using the 25-Item National Eye Institute Visual Functioning Questionnaire (NEIVFQ-25). Only 3% of students in the study were hyperopia. They found that the hyperopes were not associated with difficulty in near or distance vision function compared to emmetropes. They postulated this because the study population was young and have appropriate accommodation.

1.2.1. NEI-RQL-42

The NEI-RQL-42 questionnaire is used to evaluate the impact of various types of vision correction on the quality of life in subjects with refractive errors. It was developed by RAND corporation in 2001. No further written permission is needed for use of the NEI-RQL-42. Although RAND allowed changes to be made on NEI-RQL-42 without the written permission of RAND, but it is not recommended.

It consists of 42 multiple response questions. Each response is recorded accordingly based on the manual provided with a range from 0 to 100. The items of the questionnaire are subdivided into 13 subscales, which aim to assess the individuals' quality of life. The summarized brief explanation of each subscale according to the contents of the questions from which each category is shown in Table 1.2.

The arithmetic mean of the responses to the questions within the same scale is calculated as the score for each subscale. The arithmetic mean of average scores of all the subscales is calculated as the global score of the VRQOL in which higher scores show a better VRQOL (Hays & Spritzer, 2002; Queiros *et al.*, 2012; Shams *et al.*, 2015)

Table 1.2 A brief explanation of each subscale domain of NEI-RQL-42

No	Subscale domain	Brief explanation
1	Clarity of vision	Self-perception of corrected vision within the past 4-weeks
2	Expectations	Life improvement with perfect vision without correction
3	Near vision	Difficulty in carrying out near distance visual activities
4	Far vision	Difficulty in carrying out far distance visual activities including driving
5	Diurnal fluctuations	Difficulties and bothering with clarity of vision changes over a day
6	Activity limitations	Limitations in taking part in sports, recreational and other activities because of vision
7	Glare	Distortions around lights during the past 4-weeks
8	Symptoms	Bothering physical sensations related to vision during the past 4-weeks
9	Dependence on correction	Need for visual correction to do common daily activities
10	Worry	Concern with visual problems issue
11	Suboptimal correction	Tolerance to under optimal correction to look better
12	Appearance	Satisfaction with visual correction in esthetic appearance
13	Satisfaction with correction	Self-explanatory

1.3 RATIONALE OF THE STUDY

Asia has the highest prevalence of visual impairment secondary to refractive error. The traditional clinical judgment only assesses the visual function by visual acuity. Through this study, we are able to measure the impact of the refractive errors affecting their quality of life. Moreover, it can establish the “baseline” functioning, symptoms, and perceptions of the myopes regardless of modes of correction either spectacles or contact lenses.

There were several published studies using NEI-RQL-42 conducted in other countries such as England, Portugal, and Iran. However, VRQOL is inadequately examined among our population despite the prevalence of myopia in Southeast Asia including Malaysia is in the increasing trend.

Our target study population was undergraduate students in which the prevalence of myopia was high as demonstrated in multiple literature reviews by Asia countries. At the same time, their age group falls at common age group who wish and undergoes refractive surgery as one of the options for correcting their refractive error. The impact of VRQOL measured in the study can be used as a reference to them during preoperative counselling.

Chapter 2

Study Objectives

2.1 GENERAL OBJECTIVE

To evaluate the vision-related quality of life using NEI-RQL-42 and its associated factors among undergraduate students with myopia

2.2 SPECIFIC OBJECTIVES

- 2.2.1 To compare the score of vision-related quality of life using NEI-RQL-42 between myopia and emmetropia among undergraduate students
- 2.2.2 To compare the score of vision-related quality of life using NEI-RQL-42 between those with using spectacles and contact lens among undergraduate students with myopia
- 2.2.3 To identify the associated factors affecting the vision-related quality of life using NEI-RQL-42 among undergraduate students with myopia

Chapter 3

Methodology

3.1 RESEARCH DESIGN

A cross-sectional study

3.2 STUDY POPULATION, PLACE OF STUDY AND STUDY DURATION

3.2.1 Study population

The undergraduate students in Health Campus of Universiti Sains Malaysia (USM), Universiti Teknologi MARA Kelantan Kampus Machang (UiTM Machang), and Universiti Malaysia Kelantan Kampus Bachok (UMK Bachok) who from the following faculties:

- 1) School of Medical Sciences, USM
- 2) School of Dental Sciences, USM
- 3) School of Health Sciences, USM
- 4) Faculty of Art & Design, UiTM Machang
- 5) Faculty of Computer & Mathematical Sciences, UiTM Machang
- 6) Faculty of Information Management, UiTM Machang
- 7) Faculty of Creative Technology & Heritage, UMK Bachok
- 8) Faculty of Architecture & Ekistics, UMK Bachok

3.2.2 Place of study

Public Universities in Kelantan

- 1) Health Campus, USM
- 2) UiTM Machang
- 3) UMK Bachok

3.2.3 Study duration

From Dec 2018 until November 2020

3.3 SAMPLING AND SAMPLE SIZE

3.3.1 Sampling Method

The convenience purposive sampling method was applied for undergraduate students in the selected universities in Kelantan. The selected universities' students were invited officially through advertisement to join the study voluntarily.

Those volunteers had received an ocular examination, including measurements of presenting visual acuity and refractive errors and screening of other ocular pathologies. Those volunteers that fulfilled both the inclusion and exclusion criteria were recruited to complete the National Eye Institute/Refractive Error Quality of Life Instrument-42 questionnaire.

3.3.2 Sample Size

3.3.2.1 OBJECTIVE 1

To compare the score of vision-related quality of life using NEI-RQL-42 between myopia and emmetropia among undergraduate students.

The sample size was calculated with PS software – Power and Sample Size Calculations Version 3.1.2 by using two-mean formula, whereby:

$$z\alpha = 1.96 \text{ for } \alpha \text{ (type I error probability)} = 0.05 \text{ (two tailed)}$$

$$\sigma = \text{standard deviation} = 9.21 \text{ (Shams } et al., 2015)$$

$$\text{power} = 0.8$$

$$\Delta = \text{clinical meaningful difference} = 5$$

$$m = \text{ratio of control to experimental patients} = 1$$

$$n \text{ (numbers of the subjects)} = 70 \text{ emmetropia (54+30\% drop out)}$$

$$+ 70 \text{ myopia (54+30\%drop out)} = 140$$

There was no recent study of the prevalence of myopia run in Malaysia for the age group of our study subjects and the study population in the above study was among the Chinese populations mostly. Thus, the sample size calculation was calculated based on ratio 1:1 (emmetropia: myopia).

3.3.2.2 OBJECTIVE 2

To compare the score of vision-related quality of life using NEI-RQL-42 between those using spectacles and contact lens among undergraduate students with myopia.

The sample size was calculated with PS software – Power and Sample Size Calculations Version 3.1.2 by using two-mean formula, whereby:

$$z\alpha = 1.96 \text{ for } \alpha \text{ (type I error probability)} = 0.05 \text{ (two tailed)}$$

$$\sigma = \text{standard deviation} = 11.7 \text{ (Queirós } et al., 2012)$$

$$\text{power} = 0.8$$

$$\Delta = \text{clinical meaningful difference} = 5$$

$$m = \text{ratio of control to experimental patients} = 4$$

$$\begin{aligned} n \text{ (numbers of the subjects)} &= 70 \text{ contact lens (54 +30\% drop out)} \\ &+ 281 \text{ spectacles (216+30\%drop out)} = 351 \end{aligned}$$

Due to no available data for the prevalence study of contact lens users and spectacles users among the myopic population, the sample size was calculated based on the expert opinion with a ratio of 1:4 (contact lens: spectacles).

3.3.2.3 OBJECTIVE 3

To identify the associated factors affecting the vision-related quality of life using NEI-RQL-42 among undergraduate students with myopia.

The sample size was calculated based on multiple linear regression analysis using G Power software 3.0.10 using input parameters as below:

Test family: F tests

Effect size $f^2 = 0.15$

α (type I error probability) = 0.05

Power = 0.8

Number of predictors = 7

List of the predictors: (Hays *et al.*, 2003; Hsieh & Lin, 2016; Shams *et al.*, 2015)

- 1) Gender
- 2) Race
- 3) Course
- 4) Parental educational level
- 5) Monthly family income
- 6) Number of myopic parents
- 7) Duration of using spectacles or contact lens

Total sample size = 103

The parameters for the sample size calculation were not available in the literature. No study reported the evaluation of the quality of life using NEI-RQL-42 among university students with myopia. Therefore, the sample was calculated with G-power linear regression by estimated variables which are 7.

The total sample size was chosen based on the biggest number.

Total myopic subjects = 351

Total emmetropic subjects = 70

Total sample size = 421