ORIGINAL ARTICLE

Comparison of Improvement of Quality of Life After Using Ready-Made Spectacles and Custom-Made Spectacles in Junior High School Students in Bandung District

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ABSTRACT

Introduction: Uncorrected refractive error remains a leading cause of blindness and visual impairment among different population groups worldwide. In school children, it has a considerable impact on quality of life including social development, school performance and academic achievement that can affect their future. Management of refractive errors in developing countries is not adequate related to the cost, availability and distance of health and optical services. Hence, early detection and intervention with ready-made spectacles at the time of school children vision screening programs is expected to help solving these problems.
Objective: To evaluate outcome measure of wearing ready-made spectacles (RMS) and custom-made spectacles (CS) on children's quality of life.
Method: A non-inferiority trial with a margin of 25%, cluster-randomized trial. Children aged 11-15 years in Bandung Regency, that meet the inclusion criteria were randomized to receive RMS and CS. Main study outcome was global score on the National Eye Institute Refractive Error Quality of Life-42 after one month of wearing study glasses, comparing both group.
Result: A total of 220 eligible subject were allocated to RMS (n = 110) and CS groups (n = 110) respectively. Baseline and end line score data were available for 220 (100%) of subjects. Improvement of quality of life in RMS group was 19.48±9.33 and CS was 24.14±9.68 with D = -18.11(CI 95% -19.36 to -16.64).
Conclusion: Improvement of quality of life in RMS group is non-inferior compare with CS group

Keywords: Refractive disorders, ready-made spectacles, custom-made spectacles, quality of life.

Uncorrected refractive disorders are a major cause of visual impairment in the world and are the second leading cause of blindness in the world.[1-4]

In Indonesia, around 10% of 66 million school-age children diagnosed with refractive disorders. Based on the refractive screening program of children aged 13-14 years conducted by the Ophthalmology Community Unit National Eye Center, Cicendo Eye Hospital in 2014, the

proportion of refraction disorders was 10.1% and refractive correction with glasses was 3.5%.[5,6-9]

The quality of life according to the WHO Instrument Group is an individual's perception of his existence or position in life. Uncorrected refractive disorders will cause visual impairment and decrease visual function. This can give rise to loss of opportunities for education and job, along with low productivity and affect quality of life.[1,3,10-12]

The impact of eye disorders on quality of life has been documented in several studies. One measure that can be used to assess quality of life related to vision function is the National Eye Institute Refractive Error Quality of Life Questionnaire (NEI - RQL - 42).[13-15]

Glasses are effective visual aids. Correction of refractive disorders with glasses is widely used because it is relatively cheaper and easier to use. The most commonly used glasses are Custom-made Spectacles, that provide refractive correction in accordance with the patients' refraction status. Nonetheless, the availability of glasses is a challenge in developing countries. Based on the 2013 Riskesdas, the availability of refractive correction in rural areas was 2.6%, whereas in urban areas was 6.6%.[7,16-22]

Due to the large incidence of refractive disorders in Indonesia, an efficient and effective way to provide correction glasses is required, including the use of Ready-made Spectacles. RMS are correction glasses with spherical lenses that have a certain diopter power, use the calculation of Spherical Equivalent (SE) on astigmatism and are immediately given in refractive disorders screening.[16,18,19]

Research on the use of Ready-made Spectacles in Indonesia has never been done before. In several countries several studies have been conducted to assess the effectiveness of using Ready-made Spectacles as an alternative for correction of refractive abnormalities. These study recommended the use of Ready-made Spectacles in areas with high necessity, limited data sources and low coverage of refraction services.[19,23,24]

SUBJECTS DAN METHODS

Research Subject

This research is a non-inferiority study; cluster randomized clinical trial that has received an approval from the Ethics Commission of Padjadjaran University.
The research was conducted at Junior High Schools in Bandung District.

The inclusion criteria in this study were children aged 11-15 years with Presenting Visual Acuity (PVA) <6/12, best corrected visual acuity ≥ 6/9, refractive disorders within + 6.00 D to - 6.00 D spherical equivalent, 1.00 D astigmatism, the difference in spherical equivalent on both eyes was not more than 1.00 D and interpupilary distance was between 56 to 65 mm. Patients with other ocular disorders were excluded from this study and were referred to the hospital for further management.

The number of samples was determined based on the formula to test two proportions for non-inferiority trials with 90% power and 10% drop out estimation, so the number of samples in this study was 110 children per group.

The sample was chosen by multistage stratified cluster random sampling where samples were selected from several junior high schools in Bandung district.

From the selected cluster then randomization was carried out to determine which intervention would be given.

Validity and Reliability Test of the Questionnaire

Adaptation of Indonesian form of NEI - RQL - 42 was developed in accordance with the internationally recognized standard method. The translation process was done by the forward backward translation method and was carried out by two bilingual certified translators. A pilot test was conducted on

20 patients to assess the response and understanding of each question on the Indonesian version of the questionnaire. The validity and reliability test of the questionnaire was conducted. In this study, the questionnaire was valid and reliable.

Ophthalmology Examination

All patients that met the inclusion criteria were divided into two groups, ready-made spectacles (RMS) and custom-made spectacles (CS). Questionnaire was filled with interview method to assess quality of life related to vision before and one month after using glasses.

Statistic Analysis

Subject characteristics in both groups were compared. Improvement of quality of life after using glasses in both groups was assessed as the difference (Delta) by the Confident Interval (CI) of 95%. Non-inferiority criteria were obtained if the delta was in the non-inferiority margin of 25%.

RESULT

The characteristic of the subjects between the RMS and CS groups can be seen in table 1.

Comparison of the use of glasses at the of examination, throughout the day and satisfaction after glasses betweeen the RMS and CS groups can be seen in table 2.

The use of glasses during the examination and use of glasses throughout the day is better in the CS group than in the RMS group. The level of satisfaction of the subjects after the use of glasses in both groups is almost the same. Comparison of improvement in quality of life after using glasses in junior high school students between the RMS and CS groups can be seen in table 3.

The non-inferiority test in this study uses a margin of 25% with a value of 95% Confident Interval (CI) in both groups. Difference in improvement in quality of life in the two groups using a 25% non-inferiority margin is d = -18.11% (CI95% -19.36% to -16.64%). (Figure 1)

Table 1 Characteristic of the Research Subjects in the RMS and CS groups

Variable	Group		P value
	RMS (n=110)	CS (n=110)	
Gender			
Male	25(22.7%)	21(19.1%)	0.507
Female	85(77.3%)	89(80.9%)	
Age (years)			
Median	13	14	0.0001*
Range	11-15	11-15	
Father's Spectacles Status			
Wearing Spectacles	36(32.7%)	32(29.1%)	0.560
Not Wearing Spectacles	74(67.3%)	78(70.9%)	
Mother's Spectacles Status			
Wearing Spectacles	30(27.3%)	40(36.4%)	0.148
Not Wearing Spectacles	80(72.7%)	70(63.6%)	
Sibling's Spectacles Status			
Wearing Spectacles	28(25.5%)	28(25.5%)	1.000
Not Wearing Spectacles	82(74.5%)	82(74.5%)	
Refractive Error			
Myopia	88 (80%)	83 (75.5%)	0.366
Astigmatism	22 (20%)	27 (24.5%)	
Hypermetropia	0 (0%)	0 (0%)	
Degree of Refractive Error			
Mild	88(80%)	90(81.8%)	0.732
Moderate	22(20.0%)	20(18.2%)	
PVA			
Median	0.25	0.32	0.103
Range	0.06-0.40	0.05-0.40	

Note : Myopia: refractive disorder of myopia in both eyes, Astigmatism: the refractive disorders of astigmatism in one eye, hypermetropia: refractive disorder of hypermetropia in both eyes. RMS : Ready-Made Spectacles. CS : Custom-Made Spectacles. PVA: Presenting visual acuity. For numerical data, the p value is tested by unpaired T test if the data are normally distributed with an alternative Mann Whitney test if the data is not normally distributed. Categorical data on p values are calculated based on the Chi-Square test with an

alternative Kolmogorov Smirnov and Exact Fisher test if the terms of Chi-Square are not met

Table 2. Comparison of the use of glasses during examination, use of glasses throughout the day and satisfaction after the use of glasses in the RMS and CS groups

Variable	Group		P Value
	RMS N=110	CS N=110	
Using Spectacles during examination			
Yes	70(63.6%)	83(75.5%)	**0.057**
No	40(36.4%)	27(24.5%)	
Using Spectacles All day			
Yes	25(22.7%)	47(42.7%)	**0.002**
No	85(77.3%)	63(57.3%)	
Satisfaction			
Not Satisfied	3(2.7%)	4(3.6%)	
Less Satisfied	21(19.1%)	10(9.1%)	
Satisfied	69(62.7%)	78(70.9%)	**0.754**
Very Satisfied	17(15.5%)	18(16.4%)	

Note:
RMS : Ready-Made Spectacles. CS : Custom-Made Spectacles. For categorical data p value is calculated based on the Chi-Square test with an alternative Kolmogorov Smirnov and Exact Fisher test if the terms of Chi-Square are not met.

Table 3. Comparison of Improvement in Quality of Life Before and After Using Spectacles in the RMS and CS Groups

Variable	Group	
	RMS N=110	CS N=110
Total Score Baseline		
Mean±Std	56.77±12.44	53.82±12.08
Total Score After Using Spectacles		
Mean±Std	76.25±8.55	77.97±10.06
Delta Score		
Mean±Std	19.48±9.33	24.14±9.68

Note: RMS: Ready-Made-Spectacles. CSS: Custom-Made-Spectacles.

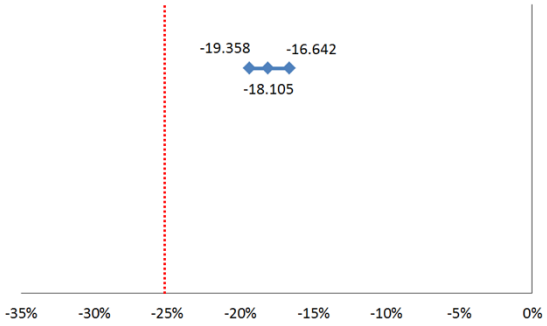

Figure 1. Non-inferiority diagram of improvement of quality of life after using RMS and CS

DISCUSSION

Screening for refractive disorders was conducted in 1009 students in four selected junior high schools in Bandung district. In this study three hundred and sixty-five students with refractive disorders without other ocular abnormalities were obtained and 220 subjects met the inclusion criteria in this study. Subjects who attended the study to the end were 220 subjects so the response rate in this study was 100%. A high response rate in a study will reduce the possibility of bias in the results of the study. The response rate in this study was 100% because the assessment was carried out for several days so that if there were subjects who were not present at the first assessment, a reassessment would be conducted on different days up to a maximum of three visits.[17,19]

There are several differences in inclusion criteria in this study compared to previous studies. Zhou et al's study had inclusion criteria for astigmatism ≤ 2.00 D and anisometropia ≤ 2.00 D with best corrected visual acuity > 6 / 7.5. In Brady's study, there was no exclusion criteria related to astigmatism. This study use inclusion criteria of astigmatism ≤ 1.00 D and anisometropia ≤ 1.00 D with best corrected visual acuity > 6/9. The reason is because in subjects with high astigmatism and anisometropia, correction by using RMS will provide less optimal visual acuity so that it is unethical if given to subjects, especially children. In addition,

the desire to wear glasses, complaints and length of adaptation to the use of RMS and CS glasses are also influenced by the magnitude of astigmatism and anisometropia as reported in the study by Zhou et al in China. In the Zhou et al. study it was found that the desire to wear RMS glasses was not inferior to CS.[17,25]

Refractive abnormalities with a higher degree affect the amount of desire to continue to wear glasses as the research conducted by Keay et al. Table 2 illustrates the type and degree of refractive disorders that are almost the same in both groups, so these do not affect the desire to wear glasses in both groups. Table 2 also describes the types of refractive disorders in the two groups. This data was raised to see the proportion of subjects with astigmatism who received corrections with SE in the RMS group which was 20%. The study by Zeng et al stated that the satisfaction of using RMS glasses was directly proportional to the magnitude of the degree of astigmatism because it affected visual acuity and uncomfortable feeling when using glasses.[3,4]

Another difference of this research with previous studies is the sampling and randomization methods. This study uses a probability sampling method with a multistage stratified cluster random sampling such as the study by Morjaria et al. This is the strength of this study because all people in the population have the same opportunity to be selected so that they could represent the population and reduce research selection bias. The sampling method differs from the study by Zeng et al, Keay et al and Zhou et al which was conducted by non-probability sampling in 5 schools enrolled in eye health screening programs or schools that were willing to take part in the study.[16,17-19]

The total mean score describing the quality of life in this study was assessed using the NEI-RQL-42 questionnaire, which has been demonstrated to have excellent internal consistency, test-retest reliability and concurrent validity has also been shown to be good. This tool has been validated in several translations and continues to be widely used in assessing the impact of refractive care on quality of life. Although this instrument has not been widely utilized in pediatric populations, we felt that it was important to employ an instrument specific to refractive disorders and its correction, and no such instruments currently exist that are specific to children.[13-17]

This study used two interviewers who were not the researchers and were first given training to equalize the perceptions of each question. The questionnaire used has been used in previous studies to assess the quality of life in the same age group and pilot tests have been carried out. The validity and reliability test have been conducted to make sure that the questionnaire can be use and understood by respondents.

Delta scores of questionnaires describe improvement in quality of life before and after the use of glasses in both groups. The difference in the improvement of quality of life between the CS and RMS groups when calculated using non-inferiority margin of <25% is d = -18.11% (CI 95% -19.36% to -16.64%). In this non-inferiority trial, we found no evidence of worse quality of life, our main study outcome, compering the CS and RMS group. This study suggested that the improvement of quality of live after using RMS is non-inferior compare with CS.

Several studies have been conducted in several countries to assess the quality of life after using RMS with questionnaire. Zhou et al. study in China stated that improvement in quality of life after using RMS was not inferior compared to CS, but this study used a 30% margin. The Brady et al. study in India used the VFQoL and Rasch questionnaire analyzes to assess quality of life in the CS and RMS groups and found that improvement in quality of life, vision function and satisfaction in both groups was almost the same.[17,25]

The strength of this study includes its randomized controlled design and high follow-up rate compared to previous studies. the limitation of this study is that there has been no standardized official training to conduct interviews with the Indonesian language version of the NEI-RQL-42 questionnaire and no analysis of the effect of the magnitude of refractive abnormalities and history of previous glasses on each group was conducted. Despite its limitation, this is the first randomized trial to assess quality of life of children wearing RMS in Indonesia.

CONCLUSSION

The improvement of quality of life after wearing Ready-made Spectacles is non-inferior compare with Custom-made Spectacles.

RECOMMENDATION

Additional research is needed to assess the relationship between types and degree of refractive disorder with quality of life improvement after wearing RMS and CS.

REFERENCES

1. Visual impairment and blindness [Internet]. World Health Organization. 2014 [cited 2018 June 14]. Downloaded from: http://www.who.int/mediacentre/factsheets/fs282/en/
2. Global data on Visual Impairments. World Health Organization. 2010. [Internet]. [cited 2018 June 14]. Downloaded from http;//www.who.int/blindness/GLOBALDATAFINALforweb.pdf?ua=1
3. Pascolini D, Mariotti SP. Global Estimates of Visual Impairment. Br J Ophthalmol. 2012;96(5):614–8.
4. Sharma A, Congdon N, Patel M, Gilbert C. School-based Approches to the Correction of Refractive Error in Children. 2012. Surv Ophthalmol, 57(3), 272-83
5. Situasi Gangguan Penglihatan dan Kebutaan. Pusat Data dan Informasi Kementerian Kesehatan Republik Indonesia. 2014. [Internet]. [cited 2018 July 23]. Downloaded from http://*www.depkes.go.id*
6. IAPB. Vision 2020 di Indonesia.[Internet]. IAPB. 2012 [cited 2018 June 13]. Downloaded from https://perdami.id/vision-2020-indonesia/
7. Syumarti, Rini M, Ratnaningsih N. Halim A, Limburgh H. Prevalence and Causes of Blindness in People Age 50 Years and Above, the Intervention Category and Action Required Reducing Blindness in West Java Province Indonesia. J Ophthalmol Clin Res. 2017;Vol 1.Issue 1.4 of 4.
8 [RISKESDAS] Riset Kesehatan Dasar. 2013. Jakarta: Badan Penelitian dan Pengembangan Kesehatan, Departemen Kesehatan, Republik Indonesia. [Internet]. [cited 2018 July 23]. Downloaded from http://www.depkes.go.id/resources/download/general/Hasil%20Riskesdas%202013.pdf
9. Siburian LN, Syumarti. Gambaran Hasil Penapisan Kelainan Refraksi Anak Sekolah Usia 13-14 tahun oleh Instalasi Oftalmologi Komunitas Pusat Mata Nasional Rumah Sakit Mata Cicendo Tahun 2014. 2015.
10. Naidoo KS, Leasher J, Bourne RR, Flaxman SR, Jonas JB, Keeffe J, et al. Global Vision Impairment and Blindness Due to Uncorrected Refractive Error, 1990–2010. Optom Vis Sci. 2016;93(3):227–34.
11. IAPB. Avoidable Blindness Refractive Error [Internet]. IAPB. 2012 [cited 2018 Jan 13]. Downloaded from https://www.iapb.org/knowledge/what-is-avoidable-blindness/refractive-error/
12. WHO. The World Health Organization Wuality of Life Assessment (WHOQOL) : Position Paper from The World Health Organization. Soc. Sci. Med. Vol.41. No. 10. 1997. Hlm. 1403-9.
13. Pakpour AH, Zeidi IM, Saffari M, Labiris G, Fridlund B. Psychometric Properties of The National Eye Institute Refractive Error Correction Quality-of-life Questionnaire Among Iranian Patients. Oman Jpurnal of Ophthalmology. 2013. Vol 6, No.1:37-43
14. Nichols JJ, Mitchell GL, Saracino M, Zadnik K. Reliability and Validity of Refractive Error-Spesific Quality-of-Life Instruments. Arch Opthalmol. 2003;121:1289-96
15. Labiris G, Gkika MG, Giarmoukakis A, Sideroudi H, Kyratzoglou K, Kozobolis VP. Psychometric Properties of the Greek NEI-RQL-42. EUR J Ophthalmol 2012;22(3):466-76
16. Morjaria P, Evans J, Murali K, Gilbert C. Spectacle wear among children in a school-based program for ready-made vs custom-made spectacles in India a randomized clinical trial. JAMA Ophthalmol. 2017;135(6):527–33.
17. Zhou Z, Chen T, Jin L, Zheng D, Chen S, He M, et al. Self-refraction, ready-made glasses and quality of life among rural myopic

Chinese children: a non-inferiority randomized trial. Acta Ophthalmol. 2017;95(6):567–75.
18. Morjaria P, Murali K, Evans J, Gilbert C. Spectacle wearing in children randomised to ready-made or custom spectacles, and potential cost savings to programmes: Study protocol for a randomised controlled trial. Trials. 2016;17(1):1–8.
19. Zeng Y, Keay L, He M, Mai J, Munoz B, Brady C, et al. A Randomized, Clinical Trial Evaluating Ready-Made and Custom Spectacles Delivered Via a School-Based Screening Program in China. Am Acad Ophthalmol J. 2009;116(10):1839–45.
20. Gudlavalleti VSM, Allagh KP, Gudlavalleti ASV. Self-adjustable glasses in the developing world. Clinical Ophthalmology. 2014. 405-13
21. Naidoo K, Ravilla D. Delivering refractive error services: Primary Eye Care Services and Outreach. Community of Eye Health Journal. 2007. 20(6), 42-4
22. Faal, H. Moving from School Screening for Refractive Error to Eye Health in Schools. 2011. Vis Dev,(1).6-7
23. Shane TS, Shi W, Schiffman JC, Lee RK. Used Glasses Versus Ready-Made Spectacles for the Treatment of Refractive Error. Ophthalmic Surgery, Lasers and Imaging. 2012. 235-40
24. Keay L, Gandhi M, Brady C, Ali FS, Mathur U, Munoz B, et al. A randomized clinical trial to evaluate ready-made spectacles in an adult population in India. Int J Epidemiol. 2010;39(3):877–88.
25. Brady CJ, Villanti AC, Friedman DS, Keay L. Visual Function after Correction of Distance Refractive Error with Ready-made and Custom Spectacles: A Randomized Clinical Trial. Wills Eye Institute Papers. Paper 14. J. Ophtha.2012. hlm 2014-20