ORIGINAL ARTICLE

The Compliance of Ready-Made Spectacle-Wear and Custom-Spectacle-Wear in Refractive Errors Screening

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ABSTRACT

Background: Uncorrected refractive errors that could seriously affect children's future. The compliance of spectacle-wear has been a problem in refractive errors management in developing countries in terms of the cost, availability and service range of both medical professionals and optical service.
Aim: To study the compliance inferiority of ready-made spectacle-wear compared to custom spectacle-wear in refractive errors screening program.
Method: Non-inferiority trial research, cluster-randomized trial was conducted to children aged 11-15 years old. Participants with corrected refractive errors (presenting visual acuity <6/12, spherical equivalent -6.00 until +6.00 Diopter (D), astigmatism ≤1.00 D, anisometropic ≤1.00 D) without other ocular abnormalities were given ready-made spectacles (RMS) and custom spectacles (CS). The observation was carried out in the first (1st) and third (3rd) month; subsequently, non-inferiority test was conducted with 20% margin.
Result: Of 1009 school children, 365 were detected with uncorrected refractive errors. Among this number, 220 participants that met the inclusion criteria were prescribed RMS (n = 110) and CS (n = 110). The most common type of refractive errors found was myopia with mild degree of refractive errors. Compliance rate on the first (1st) month for RMS-wear was 63.6% and for CS-wear was 75.5% with d = -11.9% (95% CI -17.95% until -5.85%). Compliance rate on the third month (3rd) for RMS-wear was 65.5% and for CS-wear was 72.7% with d = -7.2% (CI 95% -12.03% until -2.37%).
Conclusion: Based on the compliance observation performed in the first (1st) and third (3rd) month, there was no inferiority found among RMS-wear compared to CS-wear. This result could be used as the foundation of RMS use as an alternative for refractive errors management in refractive errors screening program to solve problems in the area of cost, availability and service range of both medical and optical service.
Keywords: Refractive errors, spectacles, ready-made spectacles, custom spectacles, school screening program

Refractive errors are the most common cause of vision impairment and the second major cause of blindness in the world. In 2010 alone, there were 108 million people with vision impairment, including blindness, as a result of refractive errors. Therefore, refractive errors are considered as one of priority components in global initiative program of VISION 2020. Nineteen million children under 15 years old are estimated to have refractive errors; 12 million of this are caused by uncorrected refractive errors that could seriously lead to their learning development, career choices and future work opportunities. The compliance of spectacle-wear among school students has

been a problem in refractive errors management. Several on-going studies in Mexico, United Kingdom, China, America, India, Oman, South Africa and Brazil have resulted in spectacle-wear compliance rate of only 50-60%. Apparently, this is shown as a significant problem in refractive errors management, particularly in developing countries, in terms of the cost, availability and service range of both medical professionals and optical service.[1–4]

Custom spectacles (CS) are a type of spectacles that provides refractive correction that matches the degree of correction, particularly axis, given in refractive status examination. Therefore, basically custom spectacles are more accurate and comfortable for the wearers. However, in large scale refractive errors screening program such as for school students, prescription of Custom Spectacles is problematic because it needs more time to make and more costly to provide. One alternative to solve this problem is by giving RMS which are a type of spectacles with spherical lens; RMS are instantly provided during community-based refractive errors screening program. Ready-made spectacles uses Spherical Equivalent (SE) calculation to astigmatism. Spherical Equivalent is calculated by adding the sum of the sphere power with half of the cylinder power.[5,6]

Some studies have found that RMS could be used as an effective way to solve refractive errors problems particularly in countries with low to medium income or rural areas with problems in logistic sector. A study in China has reported that the compliance rate of RMS-wear is equal to CS-wear after a month of observation. Same founding is also gained from another study in Tanzania that states that there is no differences in use of both types of spectacles.[2,7]

These studies can be utilized as the foundation of ready-made spectacles use as an alternative for refractive errors management in refractive errors screening program to solve problems in term of the cost, availability and service range of both medical professionals and optical service.[8,9]

Uncorrected refractive errors are considered to be a significant problem among school aged students in Bandung, West Java, Indonesia. Based on a screening process of 5.167 school children aged 13-14 in 2014, there was 10,1% children that suffered for refractive errors. Despite the fact that affordable spectacles program and ease of health access have been carried out, only 3,5% of them wore spectacles. The study on spectacle-wear compliance in Bandung city and Bandung regency has shown that the compliance rate in the city is higher than in the regency, with the former reached 41.7% and the later was 21.7%. This phenomenon happened mostly because health service facilities such as refractive examination and optical services are better in the city. With those things to consider, it was decided to conduct the study in junior high school students in Bandung regency.[10,11]

SUBJECT AND METHOD

This study of non-inferiority, Cluster Randomized Trial (CRT) has gained approval from Ethical Committee of Padjadjaran University. All participants' parents have signed informed consent to participate the study.

The study was carried out in junior high schools located in Bandung regency. Multistage stratified cluster random sampling method was used to determine the participative schools. A preliminary visit would be held in the chosen schools; they would be given brochures on the importance of spectacles wear, research information and consent letters. The study was done between August and November 2018 among school children aged 11-15 years old.

Research Team

A team of 2 refractionists, 2 doctors from specialist program of Ophthalmology Department of Faculty of Medicine of Padjajaran University, and 2 medical doctors was formed to undergo the study. The refractionists performed visual acuity examination, objective and subjective refraction examination and lens installation in RMS. The ophthalmologists carried out general ophthalmologist examination and compliance evaluation. The medical doctor filled in the research forms and gathered research data. Prior to the study, the research team had done trainings on filling forms, doing spectacles installation procedure and deciding inclusion and exclusion criteria.

Research Subject

Inclusion criteria included school children aged 11-15 years old with *Presenting Visual Acuity* (PVA) < 6/12, best corrected visual acuity ≥ 6/9, refractive errors value with *spherical equivalent* + 6.00 D until – 6.00 D and astigmatism ≤1.00 D, *spherical equivalent* difference on both eyes not more than 1.00 D and pupillary distance are in line with RMS (56-65 mm). Children with other ocular abnormalities were excluded from this study and were referred to hospitals.

Sample size was calculated using the formula to test two proportions of non-inferiority trial (https://www.sealedenvelope.com/power/binary-noninferior/) with 90% power and 10% drop out calculation. The number of minimal sample was 110 participants/group.

Samples were chosen using Multistage stratified cluster random sampling from several junior high schools located in Bandung regency with Proportionate to size method in Refractive Errors Screening program of Cicendo Eye Hospital. The first stage was to choose population unit to be the sampling frame in the form of junior high schools list of names and the students' number. Then, the list of regencies, school's names and students' number were documented in Microsoft Excel. This data was sequenced alphabetically. One more column was added to facilitate cumulative frequency which is analyzed from students number from each school. Every cluster consisted of 60 participants, therefore, four clusters were needed to get 220 samples. Before choosing the cluster, sampling interval was decided by dividing total students number with cluster number. Then, a number was randomly selected between 0 until sampling interval plus 1 with randbetween formula in Microsoft Excel. The resulted number was the starting point of the chosen first cluster. The second cluster was obtained by adding the starting point with sampling interval. The third cluster was obtained by adding the number of second cluster with sampling interval. Next cluster was obtained in similar way until the desired sample size was achieved.

From the chosen clusters, intervention program was carried out randomly to decide which classes to be examined. If the sample size of 60 has not been obtained from a particular school, an additional sample number will be taken from the nearest school. Randomization has been done to determination of treatment group in each school.

Ophthalmology Examination

The clinical examination performed this study included anamnesis, ophthalmology examination of PVA with Thumbling E Chart, and objective and subjective refraction examination with LogMAR chart ETDRS. All patients met the inclusion criteria were divided into 2 treatment groups: ready-made spectacles (RMS) and custom spectacles (CS). While patients in RMS group chose spectacles frame and would be given the lowest spherical lens strength for both eyes, subjects in CS group would be given spectacles after ordering them from an optical shop. Compliance determination took place in the first (1^{st}) and third (3^{rd}) month after the spectacles were given. The exact time of compliance evaluation was

unannounced to the participants. The evaluation was carried out by two ophthalmologists from the doctoral program in Ophthalmology Department of Faculty of Medicine, Padjajaran University.

Operational definition for this study is as follow. Presenting Visual Acuity is visual acuity using currently available refractive correction, if any. Ready-made spectacles are a type of spectacles with spherical lens which are instantly provided during community-based refractive errors screening program and they use Spherical Equivalent (SE) calculation to astigmatism. Custom spectacles (CS) are a type of spectacles that provides refractive correction that matches the degree of correction, particularly axis, given in refractive status examination. Participants are said to be compliant if they wear spectacles while examination is undergone. Not inferior means that RMS-wear result is not as good as CS-wear but is still fell under non-inferiority margin of 20%.

STATISTICAL ANALYSIS

The collected data was compiled and computerized to change into information. The input data included examination results which have been coded in computer program. First, data input was carried out using double data entry by two different people. Those two data would then be compared to see if there was a possibility of code errors, incomplete data and other inconsistence. If any discrepancies were found, correction was done subsequently.

Characteristics of research subjects would be compared between the two groups. Spectacles-wear compliance level would be evaluated based on the compliance difference (delta) between two groups with 95% Confidence Interval (CI). Non-inferiority criteria would be obtained if the acquired delta value was still under non-inferiority margin of 20%.

RESULTS

Eye examinations have been performed to 1009 school students in 4 junior high schools located in Bandung regency. Three hundred and sixty five of them were diagnosed with refractive errors without other ocular abnormalities and 220 participants that met inclusion criteria were obtained.

From the table above, it is shown that the number of female was more than male in both groups. Spectacles status of parents and siblings were the same. Also, both parents were mostly literate. As for the analysis of research subject characteristics, the value of $p>0.05$ for every variable was obtained (Table 1).

The most common type of refractive errors detected in this study was myopia. Astigmatism in RMS group was 20%; it means that this 20% subjects used *Spherical Equivalent* calculation for the spectacles correction. The most common degree of refractive errors detected in this study was mild degree.

Non-inferiority test in this study used 20% margin with 95% Confidence Interval (CI) in both groups. Non-inferiority test was referred to compliance difference (delta/d) between both groups (Figure 1).

Spectacle-wear compliance rate in RMS group in the first month was 63.6% (95%CI 54.6% until 72.6%) while in CS group it was 75.5% (95% CI 67.5% until 83.5%). Non-inferior status is measured by the value of d (CS-RMS) < 20%. The delta value between both groups in the first months was d = -11.9% (95% CI -17.95% until -5.85%) (Figure 4.1). Spectacle-wear compliance rate in RMS group in the third month was 65.5% (95%CI 56.6% until 74.4%) while in CS group it was 72.7% (95 CI% 64.4% until 81.0%). Non-inferior status is measured by the value of d (CS-RMS) < 20% with d = -7.2% (95% CI -12.03% until -2.37%) in the third month (Figure 1).

Table 1 Research Subject Characteristics of both groups

Variables	Group		p value
	RMS (n=110)	CS (n=110)	
Gender			**0.507**
Male	25(22.7%)	21(19.1%)	
Female	85(77.3%)	89(80.9%)	
Spectacles status of father			**0.560**
Yes	36(32.7%)	32(29.1%)	
No	74(67.3%)	78(70.9%)	
Spectacles status of mother			**0.148**
Yes	30(27.3%)	40(36.4%)	
No	80(72.7%)	70(63.6%)	
Spectacles status of siblings			**1.000**
Yes	28(25.5%)	28(25.5%)	
No	82(74.5%)	82(74.5%)	
Illiterate status of father			**1.000**
Yes	2(1.8%)	1(0.9%)	
No	108(98.2%)	109(99.1%)	
Illiterate status of father			**0.247**
Yes	3(2.7%)	0(0.0%)	
No	107(97.3%)	110(100.0%)	
Refractive Errors Type			
Myopic	88 (80%)	83 (75.5%)	
Astigmatism	22 (20%)	27 (24.5%)	
Hypermetropic	0 (0%)	0 (0%)	
Refractive Errors Degree			
Mild	88 (80%)	90 (81.8%)	
Moderate	22 (20%)	20 (18.2%)	
Father's Education level			**0.331**
Elementary School	11(10.0%)	10(9.1%)	
Junior High School	15(13.6%)	12(10.9%)	
Senior High School	61(55.5%)	53(48.2%)	
University	23(20.9%)	35(31.8%)	
Mother's Education level of			**0.185**
Elementary School	13(11.8%)	11(10.0%)	
Junior High School	30(27.3%)	18(16.4%)	
Senior High School	50(45.5%)	57(51.8%)	
University	17(15.5%)	24(21.8%)	

DISCUSSION

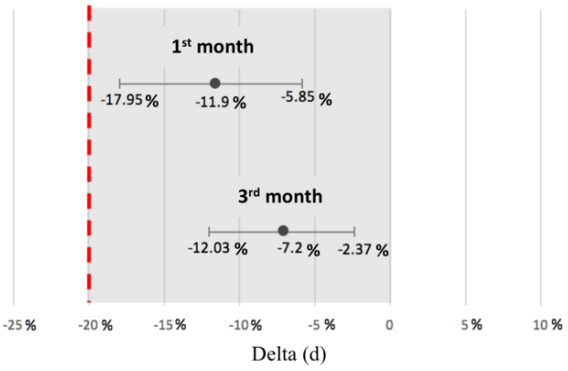
Eye examinations have been performed to 1009 school children in 4 junior high schools located in Bandung regency. Three hundred and sixty five of them were diagnosed with refractive errors without other ocular abnormalities and 220 participants that met inclusion criteria were obtained. Percentage of participants following the three-month-study was 100% which was 220 children. Based on the data, response rate of this study was 100%. The higher the response rate of a study, the lower the bias possibility of the result will be. Response rate of this study was significantly higher than previous RMS studies. Morjaria et al. announces 79.3% response rate due to the fact that some participants are transferred to other schools.

Response rate in a study by Zeng et al. is 83.6% because some students are absent on the observation days and some spectacles were broken. The 100% response rate was achieved because the examination time was conveniently held before the end of school year and the examination was conducted in several days to avoid the issue of students being absent. These ensure all participants can follow the study fully during the three months period.[2,6]

Table 2. Spectacle-wear compliance rate in RMS and CS group

Variables	Group	
	RMS N=110	CS N=110
First month compliance		
Compliance	70 (63.6%)	83 (75.5%)
Non compliance	40 (36.4%)	27 (24.5%)
Third month compliance		
Compliance	72 (65.5%)	80 (72.7%)
Non compliance	38 (34.5%)	30 (27.3%)

Sample size in this study was 220 children; the calculation of sample number was done by referring to sample number calculation program of non-inferiority research with 90% power test and 5% signification rate. This sample size is less than other previous studies conducted by Morjaria et al. (363 subjects), Zeng et al. (414 subjects), and Zhou et al. (542 subjects). Less sample size is needed in his study because of higher prevalence of refractive errors (10-15%). Compared to Morjaria et al. with prevalence of 2.6%, more samples are needed for their research. Also, the sample size in this study is different form Zhou et al; the reason is because Zhou et al. compares between 4 treatment groups by considering RMS treatment by participants.[2,6,12–15]



Note:
d = compliance difference CS-RMS (p1 – p2)

Fig 1. Non-inferiority diagram of the compliance test in the 1st and 3rd month

In the first month, while the compliance rate in RMS-wear was 63.6%, it reached 75.5% in CS-wear. Compliance rate in RMS-wear in the third month was 65.5% whereas in CS- wear it was 72.7%. It means that compliance rate in RMS group was lower than in CS group; however, the compliance difference between these two groups was still inside non-inferiority margin (d = < 20%). The compliance difference was d = -11.9% (95% CI -17.95% until -5.85%) in the first month and d = -7.2% (95% CI -12.03% until -2.37%) in the third month. This results showed that compliance rate of RMS-wear was not inferior compared to CS-wear in both first and third month after spectacles were given. The rise in RMS-wear compliance rate in the third month was possibly because of participants adaptation use of RMS.

Other studies on RMS compliance have been carried out in several countries. Morjaria study shows compliance rate of 75.5% (RMS) and 73.6% (CS). This states that RMS compliance was not inferior to CS. However, it can not be confirmed that the result is equal or superior although the result for RMS group is higher than for CS group. The value of d was 1.8% (95% CI -7.1% until 10.8%) with 10% margin. A Chinese study by Zeng et al. reports that compliance rate of 46.9% in RMS-wear compared to 51.5% in CS-wear ($p>0.05$) has been found. The study uses comparative test to analyze compliance rate between two groups. comparative test was performed to compare differences between two treatments; however, it can not decide inferior or superior status like the one used in this study with 20% margin for inferior status. [2,6]

Zeng et al. study has inclusion criteria of astigmatism until 2.00 D and anisometropic until 2.00 D. It is because higher degree of refractive errors has higher compliance rate compared to low degree ones. This factor also influences the eagerness of spectacles wearers to constantly wear them. This is proven in Keay et al. study which states that in RMS group 90% children are eager to be constant wearers while for CS group the tendency is as high as 97% ($p<0.05$) with

inclusion criteria of astigmatism <2.00 D and anisometropic <1.00 D. However, final visual acuity in RMS compared to CS in astigmatism ≥ 0.75 D and anisometropic >1.00 D is significantly different ($p<0.001$) with complaint of blurry vision experiences by participants. The eagerness of spectacle-wear, complaints and length of adaptation time among RMS and CS groups are also influenced by astigmatism size and anisometropic difference as reported in a study by Zhou et al. in China. This study shows that the eagerness to wear RMS is not inferior compared to CS. Based on this, the condition of astigmatism >1.00 D and anisometropic >1.00 D in one or both eyes is an important factor in RMS study. Therefore, inclusion criteria in this study includes astigmatism and anisometropic limit of 1.00 D, which is the same as the study by Morjaria et al. in India.[2,6,9,12]

The degree of refractive errors is an important factor that influences compliance rate of spectacle-wear. Table 4.2 shows that the degree of refractive errors in both groups was not different, as a result it did not affect compliance rate. The same table also gives data on type of refractive errors on both groups to see the proportion of participants from RMS group that received correction with SE (20%). Zeng et al. states that the satisfaction of RMS-wear is greatly related with participants' astigmatism degree because of blurry vision complaint when wearing RMS.[1,2]

The difference between this particular study with previous others lies in sampling method and randomization. Probability sampling with multistage stratified cluster random sampling was used in this study. This is one of the strong point on this study because everyone in the population has a chance to be a participant, thus it will reduce selection bias. In contrast, Zeng et al., Keay et al., and Zhou et al., conduct non-probability sampling in 5 schools listed in eye health screening program or schools willing to join the study.[2,6,9,12]

The type of randomization used in this study was cluster and single-masked randomization. This is different from other studies's randomization which is done upon every participant and is double-masked. The benefit of cluster randomization is to prevent influence among each participant receiving different treatment; also it easier to be performed on participants with similar level particularly in term of cost and treatment giving process. This has come into consideration when deciding to use cluster randomization method to avoid participants knowing treatments given as a result of time difference when providing CS and when supplying and distributing RMS. On the other hand, the drawback of cluster randomization is the possibility of selection bias and subject variation or imbalance among clusters.[2,6,9,12,16]

Non compliance rate obtained in the first month in RMS group reached 36.4% while in CS group the figure was 24.5%. In the third month, non compliance rates in RMS and CS group were 34.5% and 27.3%. This proved that many children were not compliant to constantly wear spectacles. It is true that spectacle-wear compliance is considered low and this fact has been reported by countless studies done in various countries.[17,18]

There are various factors associated with non compliance wear of spectacles. The most common reasons are broken/lost spectacles, appearance concern, the myth that wearing spectacles will worsen eye sights, spectacles are kept at home and are only worn under specific condition, and parents influence. Keay et.al also describes in their study that reasons for non compliance wear of spectacles are complaints of uncomfortable use of spectacles and broken spectacles, which appear on both groups. These reasons show that factors behind non compliance wear among RMS-wear and CS-wear are the same even though RMS have limited type of spectacles, limited pupils distance and different spherical lens measurement to correction value during clinical

examination. However, this hypothesis needs to be proved in future studies.[2–4,19]

This study resulted in higher response rate and longer observation period compared to other studies which only performed in one month observation. Compliance determination criteria is one of the strength of this study; compliance status will be obtained only when participants wear the spectacles during the observation period. It is different from Zeng et al. and Morjaria et al. studies; participants can obtain the compliance status whether they wear them or did not wear them but only bring them to school during the assessment period.[2,6,9,12]

The limitation of the study is that the compliance examination was performed only at school during the time of learning hours. There is no guarantee that participants constantly wore the spectacles while they were at home doing other activities.

CONCLUSION

Based on the compliance assesment performed in the first (1^{st}) and third (3^{rd}) month, compliance rate of RMS-wear was not inferior compared to CS-wear.

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