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Comparative Analysis of Satisfaction with the Use of Ready-Made Spectacles and Custom-Made Spectacles among School Children in Nigeria: A Randomised Controlled Trial

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Abstract
Refractive error is an important cause of visual impairment in Cross River State (CRS), Nigeria. Optical services and spectacles are not readily available to school children for the treatment. The aim of this study was to compare satisfaction with the use of ready-made spectacles and custom-made spectacles in the treatment of refractive error for school eye health programme. A one month double-blinded randomised controlled trial was used to evaluate satisfaction, symptoms, vision and planned continued use of ready-made and custom-made spectacles in school children 6 -17 years with ≥ 1 diopter of uncorrected refractive error. The sample size for each arm was 63. This research was funded by African Vision Research Institute (AVRI). Full ethical approval was obtained from the ethics committee CRS Ministry of Health, Nigeria. Data was analysed using SPSS and EPI info. Out of the 2110 children refracted with non-cycloplegic method, 243 (11.5%) has significant refractive error and only 104(82.5% response rate) met the inclusion criteria for the intervention study. There was no difference (p >0.05) in satisfaction (96.2% vs 96.2%) and symptoms (headache 5.8% vs7.7%; eye strain 3.8% vs 1.9%) in the use of ready-made vs custom-made spectacles to the 1 month follow up. Ready-made spectacles are recommended for eye health programmes in schools because it is a cost effective strategy for treatment of refractive errors. The ready-made spectacles should be available in different frame pupillary distance for various powers to reduce discomfort associated with frame induced prismatic effect.
Keywords: Eye health, vision care, school-aged children, ready-made spectacles, custom-made spectacles

1. Introduction

According to a release by World Health Organization (2006), “it has been estimated that, of the 153 million people worldwide affected by uncorrected distance refractive error, 8 million are blind and 145 million have significant distance visual impairment. At least 13million of them are children” (Sharma, Congdon, Patel, & Gilbert, 2012) Nearly 90% of all people with uncorrected refractive errors live in low and middle income countries. In many low- and middle-income countries, “there is inadequate refractive error services for the many people who are currently either blind or visually impaired because they lack a pair of spectacles”(Naidoo & Ravilla, 2007). According to Faal (2011), there is a global estimate that places the burden of vision correction need among school-aged children at 815 million (Faal, 2011). Treatments are not readily available due to restricted coverage of eye health services and cost. Ready-made spectacles were therefore recommended for low income countries to address the problem, however, the satisfaction and visual performance with the use of the ready- made spectacles amongst school-aged children are yet to be evaluated in Cross River State and in Nigeria. In refractive error research, “the lack of standard definitions makes comparisons between different studies difficult. For example, hyperopia may be defined as greater than +2.00D in one study and less than +2.00 in another study” (Williams et al., 2008), whereas in another a definition of greater than +0.50D may be used (Azizoglu, Junghans, Barutchu, & Crewther, 2011; Junghans, Crewther, Kiely, & Crewthe, 2002).

Refractive errors are an avoidable cause of visual impairment and are easily correctable with spectacles or contact lenses(Gudlavalleti, Allagh, & Gudlavalleti, 2014). “But the provision of spectacles is a major challenge in the developing countries due to the scarcity of human resources for refraction and optical services, lack of access to refractive services and the cost of spectacles” (Gudlavalleti et al., 2014; Karnani, Garrette, Kassalow, & Lee, 2011). “Treatment of uncorrected refractive error improves vision and correction with spectacles is the most preferred by patients with satisfaction rate of about 74.85 SD 22.55” (Hays, Mangione, Ellwein, Lindblod, Spritzer & McDonnell, 2003). Various methods have been tried to reduce cost. One of the commonest is the use of ready- made spectacles (RMS). “RMS reduce costs as they are produced in bulk with same refractive power in both eyes, common frames and limited diopter steps”(Brady, Villanti, Gandhi,

Friedman, & Keay, 2012). Spectacles are usually made to order (Custom-made spectacles CMS). However due to lack of adequate resources and a high level of need in developing countries, ready-made spectacles may be preferred. Ready-made spectacles (RMS) have advantages but to my knowledge there is paucity of research on the acceptability of RMS in comparison with CMS in Nigeria.

A number of studies have documented findings on the use of ready-made spectacles(Keay et al., 2010; Maini, Keeffe, Weih, McCatry, & Taylor, 2001; Zeng et al., 2009). "In a one month double blinded randomized clinical trial to evaluate visual performance and satisfaction with RMS and CMS in Chinese children aged 6 – 17 years of age with ≥ 1 diopter (D) of URE, the study recommended the use of RMS for the delivery of refractive services in settings where there is a high level of need, limited resources and low access to refractive services"(Zeng et al., 2009). The study in Australia, which considered adult populations, concluded that 20% of the need for spectacles could be easily met by RMS, but the remaining 80% of need would have to be met by CMS (14)(Maini et al., 2001). In a similar study carried out in Haiti and Belize, by Shane *et al* (2011), found that RMS allow for effective treatment of URE in adults in the developing world. A similar study in India and found that RMS and CMS were highly acceptable once the high astigmatism and those with anisometropia were excluded (Shane, Shi, Schiffman, & Lee, 2012). However the need for custom-made spectacle was not as high as that reported in the Australian study (Keay et al., 2010).

A study was conducted to compare corrected vision with self-refraction without cycloplegia and refraction by an ophthalmologist with cycloplegia among children 12 to 18 years. "The result showed that self-refraction was within one line 6/6 visual acuity in 98% of students. This shows that RMS is an effective method of correcting refractive error in children"(Zhang et al., 2011). The literature review, revealed no published data no evaluation of RMS in Nigeria. In view of lack of information from the country and importance of detecting and treating refractive errors in school children, effort was made in this study targeting the children from public and private schools in Cross River State to determine satisfaction with the use of ready-made spectacles and custom-made spectacles in the treatment of refractive error for school eye health programme in Nigeria.

2. Materials and methods

Nigeria with a population estimate of 178 million people based on 2006 census data projected to 2015 is the largest country in black sub Saharan Africa. In Nigeria, there are all together 36 states and the federal capital territory Abuja. Cross River State, the study area, is one the 36 states in Nigeria, located in the south – south geo political zone, with a population estimate of about 3.1million (50.3%males and 49.97% females) (NPC, 2006). The prevalence of blindness in Cross River State according to a state survey report 2006 is 0.8% with 8.7% having low vision (presenting VA <6/18 to < 6/60), and the major causes of low vision (visual impairment) in this study included refractive error, glaucoma, cataract, and anterior uveitis (Nkanga, Asana, Duke, Ekpenyong, & Etim, 2007). The study was an intervention study using double-blinded randomized controlled trial to compare difference in satisfaction and visual performance with Ready-made spectacles and custom-made spectacles in children aged 6-17 years with ≥ 1 diopter of uncorrected refractive error (myopia, hyperopia, and astigmatism) The eligibility criteria were as follows; they should have completed the diagnostic test, they should have refractive error of ≥ 1 diopter (D). The exclusion criteria was the presence of an underlying pathological eye condition, astigmatism of >2.00D and anisometropia of >1.00D.

2.1 Sample size determination

The sample size for the intervention Randomised Controlled Trial was determined using a test of difference in proportions and considering alpha and beta errors. The appropriate formula used for calculation of the sample size of the children was $n = (Z\alpha + Z_{\beta})^2.2.\bar{p} (1-\bar{p})/d^2$ (17).

Where

n = sample size

$Z\alpha$ = Standardized normal deviate at 95% level of confidence is 1.96

Z_{β} = Z- value corresponding with Beta error of 20% (80% power) is 0.84

$\bar{p}$ = mean proportion of satisfaction with treatment p^1 (0.97) and p^2 (0.82) is 0.90 (9)

$1 - \bar{p}$ = mean proportion of not satisfied with treatment $p^1 - p^2$ is 0.10

$\eth$ = difference to be detected ($p^1 - p^2$) is 15%

Applying the above formula, $n = (1.96 + 0.84)^2.2. (0.90) (0.10) / (0.15)^2 = 63$

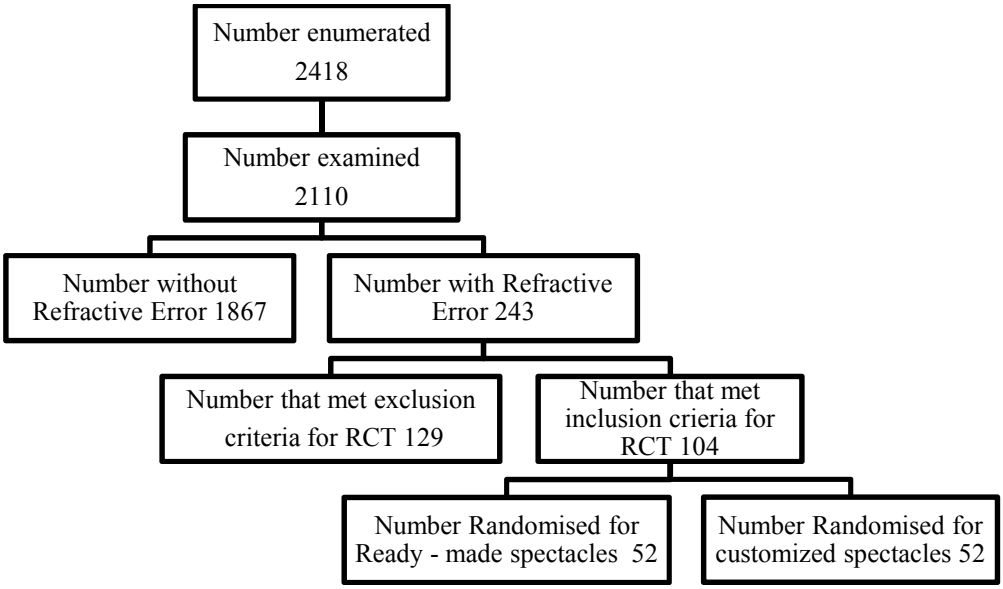

Figure 1:.Flow chart for the Randomized Controlled Trial (Study Conceptual Framework)

A total of 63 subjects per group x 2 groups =126 subjects who met the inclusion criteria were used for the intervention study. The sample size for each group as calculated was 63, making a total of 126 children, but a total of 104 children who met the eligibility criteria were enrolled. The list of 104 eligible students were randomized into the two different treatment groups; ready-made spectacles and customized spectacles respectively. The randomization process was blind to both the researcher and the children receiving the treatment. This was done by an external person not involved in the study. The initial randomization was done by allocating the numbers one and two to each child to separate the children into two treatment groups one and two, then using two pieces of folded papers with RMS and CMS written in each respectively, the first paper chosen was assigned to group 1, while the second was assigned to group 2. The first paper that was picked was RMS and the second was CMS, this resulted in 52 children in group 1 (odd numbers) who received spherical equivalent of their refractive error in a ready-made form with same prescription both eyes. While the group 2 (even numbers) also made up of 52 children got the full sphero-cylindrical prescription (custom-made spectacles).

The primary outcome variable was satisfaction and willingness to continue the use of the spectacle, while secondary outcome measure was visual performance through visual acuity. Study participants were evaluated when they receive their spectacles and after one month of wear. To determine their satisfaction and acceptability of their spectacles, study participants were asked a range questions (which included history of blurred vision, distorted vision, dizziness, eye strain, nausea) when they first received their glasses and one month after use. Visual acuity was compared on receipt of spectacles and one month after use to determine visual performance.

For ethical reasons, students who had refractive error but were not eligible for the intervention study were given spectacles after evaluation. Those with significant refractive errors less than or equal to the inclusion criteria were given ready- made spectacles, while those who are within the exclusion criteria were given customised spectacles. Data were analysed with intent to treat. Two students who were lost to follow up due to the change of school were followed up in their new school. There was a case of a lost or misplaced spectacle, which was replaced the next day.

TABLE 1: Baseline characteristics of children receiving Ready-made spectacle (RMS) and Custom-made spectacles (CMS)

Variable	RMS n=52 (%)	CMS n=52 (%)	χ^2	p-value
Age				
6-11	**36.6**	**23.1**	**1.69**	**0.19**
12-13	**65.4**	**76.9**		
Gender				
Boy	**32.7**	**51.9**	**3.94**	**0.047**
Girl	**67.3**	**48.9**		
Class				
1	**32.7**	**21.2**	**3.38**	**0.18**
2	**32.7**	**26.9**		
3	**34.6**	**51.9**		
Diagnosis				
Blurred	**0.00**	**0.0**		**1.0**
Distorted	**0.00**	**0.0**		**1.0**
Dizzy	**3.8**	**1.9**	**0.34**	**0.56**
Eyestrain	**3.8**	**1.9**	**0.34**	**0.56**
Headache	**5.8**	**7.7**	**0.15**	**0.69**

Note; baseline characteristics of children who received Ready–made spectacles (RMS) and Custom-made spectacles (CMS) were similar except for gender

TABLE 2: Satisfaction with the use of ready-made and custom-made spectacles among school children with significant refractive error

Ready-Made Spectacles N=52				**Custom-made Spectacles N=52**				
	D1			D2			D_1-D_2	
	Pre	Post	Diff	Pre	Post	Diff	Diff/Diff	P-value
Blurred Vision	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.000
Distorted Vision	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.000
Headache	5.8	0.0	5.8	7.7	0.0	7.7	1.9	0.695
Eye Strain	3.8	0.0	3.8	1.9	0.0	1.9	-1.9	0.560
Nausea	0.0	0.0	0.0	1.9	0.0	1.9	1.9	1.000
Planned CU	92.3	96.2	3.9	96.2	96.2	0.0	-3.9	0.040
Very Satisfied	96.2	100	3.8	96.2	100	3.8	0.0	1.000
Moderately Satisfied	3.8	0.0	3.8	3.8	0.0	-3.8	0.0	1.000
Not Satisfied	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.000

Pre – On the day spectacle was given
Post – After one month of spectacle use
Note; there was no statistically significant difference in the variables tested between children who received RMS and those who received CS on the day spectacle was given and one month after use.

2.2 Quality assurance for reliability of data collected.

Calculation of induced prisms by Ready – made spectacles

In order to rule out induced prism as a possible cause of uncomfortable vision with spectacles especially with ready-made spectacles, the induced prism was calculated in 10% of children who received ready-made spectacles. This was done by measuring the patient PD and frame PD, which was then used to calculate the induced prism using Prentice's formula and compared with the allowable tolerable prism. According to Toit, Ramke and Brain (2007), the allowable tolerable prism for wearers of ready-made spectacles are ≤ 1.0 prism dioptre base- out (BO) or ≤ 1.0 prism dioptre base -in (BI) (18). The range of prism induced for the wearers of the RMS found in this study were ≤ 1.0 BO and BI induced prisms respectively and as such was not significant enough to induce any discomfort. The maximum was 0.5 and the minimum was 0.2.

This result was expected because the ready – made spectacles were prepared in 6 different frame sizes for same power, which afforded us the opportunity to give ready – made spectacles that were nearly same pupillary distance (PD) with that of the patient. The resultant effect is the reduced prismatic effect induced by frame size and a reduced discomfort with spectacle use.

Data were entered and cleaned using the IBM SPSS (Version 20) software. For Statistical analysis,

various software such as Epi Info 3.5.4, IBM SPSS and WinPepi, were used depending on the peculiar analysis. The difference in difference approach was used to compare satisfaction with the use of ready-made spectacles when compared with the use of custom-made spectacles. Changes in which p-values were 0.05 or less were considered statistically significant. Data analysis by 'intention to treat' was used for the randomized controlled trial. For Quality Assurance, strength of agreement between the measurements made by the researcher and the research assistants was evaluated using Cohen's Kappa statistic and paired t- test.

3. Results

The conceptual frame work for this study is presented as a flow chart to explain at a glance the concepts employed in this study to arrive at the results, starting from the cross sectional study design to the randomized double blinded control trials. Of the 2110 children examined, only 104 out of the 243 with refractive error met the inclusion criteria for the intervention study and were randomized into the two treatment groups, 52 received Ready-made spectacles while 52 received custom-made spectacles (Figure 1). The mean age of all children was 11.69±3 years (Figure 2).

Vision assessment of the children identified 243 of 2110 children with refractive error and only 104 (82.5%) met the inclusion criteria of refractive error ≥ 1.00D of spherical equivalent. The base line characteristics of the randomized groups for ready-made spectacles and custom-made spectacles were determined. Social, demographic and ocular parameters were the same in the groups, except for gender that was marginally significant. In the ready- made spectacle group, 32.7% were male and 67.3% were female while in the customized group, 51.9% were male and 48.1% were female. This difference was marginally significant at 95% significant level p = 0.047 (Table 1).

Comparison of satisfaction with the use of ready-made spectacles and customized spectacles was analysed using difference of difference analysis and the result has shown that there was no differences (p >0.05) in satisfaction. Those who were very satisfied with ready-made spectacles and with custom-made spectacles on the day spectacles were given were the same (96.2% vs. 96.2%), moderately satisfied (3.8% vs. 3.8%), not satisfied (0.0% vs. 0.0%), planned continued use of spectacles (92.3% vs. 92.2%) symptoms (headache 5.8% vs. 7.7%; eye strain 3.8% vs. 1.9%; nausea 0.0% vs. 1.9%) and no complain of blurred and distorted vision was recorded for the two groups.

After one month of use of the spectacles, the variables were measured again, satisfaction rate increased to 100% for both the ready-made and customized groups, planned continue use remained at 96.2% and that was the only variable that had significant difference in the two groups (p =0.040). There was no complaint about blurred and distorted vision, no headache, eye strain and feeling of nausea (Table 2)

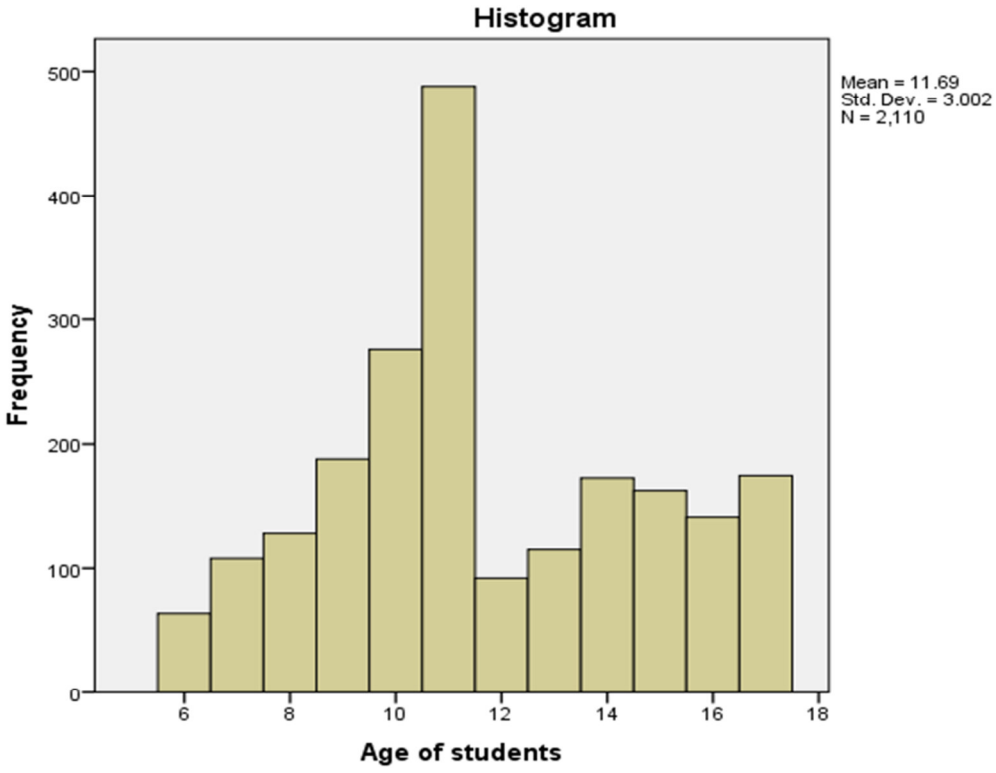

Figure 2: Age distribution of school children

4. Discussion

Result of this study has shown that there is no difference between satisfaction with the use of ready-made spectacles and custom-made spectacles among school children in the treatment of refractive error. The result of this study is comparable to the result from a study by (Zeng et al., 2009) in China, who also recommended the use of RMS in school based refractive services programme. Similar studies carried out on adult population also recommended the use of RMS (Keay et al., 2010; Maini et al., 2001; Shane et al., 2012). Ready-made spectacles are a low cost approach to provision of spectacles (Brady et al., 2012) in developing countries like Nigeria. The limitation in this approach is the restricted choice of frames which can be reduced by producing the lenses in a range of assorted frames for a particular lens power as was used in this study. The whole idea is to encourage usage. Another limitation is non-correction of anisometropia and astigmatism of higher degree. The study has shown that the use of spherical equivalent and binocular balancing in the two eyes, with certain range of anisometropia (≤ 1.00)and astigmatism (≤ 2.00) is tolerable.

Result of this study has also shown that about 43% of spectacle need can be satisfied with RMS. This is higher when compared with the study conducted in Australia (Maini et al., 2001). The study in Australia was among the adult population and that could account for the difference. The use of self-adjustable glasses is also being recommended for developing countries due to the paucity of optical services, but compared with RMS, it is more expensive and not readily available (Gudlavalleti et al., 2014). The study therefore recommends RMS for the delivery of refractive services in schools in the developing countries particular in Africa where there is low access to refractive services and limited human and material resources for eye care.

5. Conclusions

Although Visual performance with visual acuity may seem better with custom-made spectacles there was no significant difference in satisfaction between the use of RMS and CMS among school-age children. Nearly 50% of the spectacle need was met. RMS is therefore recommended for correction of refractive errors with ≤ 1.00D of anisometropia and ≤ 2.00D of astigmatism. Provision of RMS for school health programme will make the spectacles readily available and at a reduced cost to children who need them and the spectacle coverage which is currently revealed to be very low will be improved.

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