The effectiveness of the custom spectacle and ready-made spectacle interventions in improving visual acuity: Study Protocol for non- Inferiority Double Blind Randomized Clinical Trial among school children in Yangon Region, Myanmar

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Abstract- Refractive error (RE) is a very common eye disorder among school children, resulting in impaired vision in 2.6 billion people globally. Among them, 312 million were under 19 years of age. Programs have been rolled out in low-income settings, providing spectacles to school children with uncorrected refractive error(URE). However, for a program to meet the needs, spectacles dispensed need to be affordable, accessible, feasible, and visually functionally improvable. Different studies have shown different findings on compliance, visual acuity improvement and cost of provision of the ready-made spectacles (RMS) and the custom-made spectacles (CS), spectacles with the correction specifically required for that individual. In Myanmar setting, there has not been studied the effectiveness of ready-made spectacles. This non- inferiority double blind randomized clinical trial aims to determine the compliance of the prescribed spectacles and to test non-inferiority in improving visual acuity between the ready-made and custom spectacle interventions to treat uncorrected refractive error among school children in Myanmar. The accurate, up-to-date, evidence-based data on the prescription of spectacle options will fill the current knowledge gap of the main policymakers, the Ministry of Education, the Ministry of Health and Sports, and related partners who are planning to provide school-based vision care services for school children in Myanmar near future.

Index Terms- Non- Inferiority Double-Blind Randomized Clinical Trial, Refractive Error, School Children, Myanmar

I. INTRODUCTION

The refractive error(RE), or ametropia, is a defect in the lens' ability of the eye to focus an image. RE is a very common eye disorder among school children, resulting in blurred vision, which is sometimes so severe, leading to visual impairment. The World Report on Vision 2019 stated that global estimates of the number of people affected by myopia were 2.6 billion, and among them, 312 million were under 19 years of age[1], which is projected to increase to 324 million by 2025[2]. Promoting and improving the eye health of all, including children, contributes to several of the Sustainable Development Goals[3]. The estimated pool prevalence of myopia, which is the most prevalent type of RE, was 4.9% in South–East Asia[4]. Urban school children have high myopia prevalence and are observed as major public health[5,6,7].

Programs have been rolled out in low-income settings, providing spectacles to people living with uncorrected refractive error(URE) in South East Asian countries like in Cambodia[8] and Indonesia[9]. For a program to meet the needs of a population living with URE, spectacles dispensed need to be affordable, accessible, easily obtainable, well tolerable, durable, cosmetically acceptable, and visual functionally improvable. School-based screenings for refractive error and on-site spectacle provision is one solution outlined in the World Health Organization Vision 2020 targets for control of blindness in children. In some countries, to overcome cost constraints, ready-made spectacles (RMS), spectacles without astigmatic correction and with the same refractive error in both eyes, have been

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used for spectacle delivery programs in some low-resource settings[10]. It is assumed that the RMS program carries an inventory of lower cost and new spectacles of commonly required powers, which can be provided to patients on the spot compared with the custom spectacles(CS), that is, spectacles with the correction specifically required for that individual, which can provide full correction of astigmatism and anisometropia as an advantage; however, it is expected as a costlier option[11].

Some countries like in India; school eye-screening programs CS regardless of severity or type of RE. These spectacles are not only more expensive to dispense than ready-made spectacles(RMS) but also require dispensing opticians, and cannot be dispensed immediately in schools as a one-stop service. However, on the other hand, when RMS is offered free, they are worn by less than 1 in 6 children and were available for use at school in less than half of cases for parents' ignorance, glasses were socially unacceptable, and broken or lost[12]. A cost-effectiveness analysis of a double-masked randomized controlled trial to determine the relative cost-effectiveness of offering RMS and CS to treat URE among adults found that there was no significant difference between the effectiveness in improving visual acuity between them, but the CS was over four times the price of the RMS per patient. According to this study, the RMS program was found effective and cost-effective option than CS, providing further support for including RMS in programs to address URE[13]. Regarding compliance among school children, another randomized clinical trial of a school-based program RMS versus CS was studied in Banglor, India, found that the proportions in the RMS group were 'not inferior' when wearing spectacles compared to the CS group after 3 to 4 months of trial. Follow-up rates at 3 to 4 months were also similar to 78% in the RMS group versus 79% in the CS group[14].

Similar findings were seen in China's study. In uncorrected visual acuity ≤20/40 in the better-seeing eye group showed a 91.1% improvement by ≥3 lines of visual acuity with refractive correction and the ≤20/50 group showed a 97.4% improvement by ≥3 lines, suggesting that RMS could substantially alleviate visual morbidity in two-thirds or more of visually impaired schoolchildren in China[15]. Conversely, visual acuity was lower in RMS than in CS in the other study in China, but there were no differences in the rate of wearing after the 1-month visit among students with a predominantly simple myopic refractive error[16].

However, dispensing RMS remains problematic and more expensive owing to the logistics cost resulting from choosing different varieties of the spectacle frame and powers of spectacle, expense, and reports of low compliance [12, 17,18]. Therefore, RMS might not always be assumed to be a feasible, affordable, and preferable option compared to CS. Moreover, depending on the severity of visual impairment and lack of correction for astigmatism and anisometropia, the percentage of children who could be accommodated in gaining visual acuity with RMS might differ from CS. In the Myanmar setting, there have been no visual acuity evaluations examining the effectiveness of ready-made spectacles. Therefore, it is fruitful to investigate the relative effectiveness of offering spectacles, either RMS or CS, in Myanmar. The accurate, up-to-date, evidence-based data on the prescription of spectacle options will fill the current knowledge gap of MOHS and related partners, who are planning to provide school-based vision care services for school children in Myanmar near future.

Aims of the study

This study aimed to determine the relative effectiveness of offering spectacles to treat uncorrected refractive error and to test non-inferiority in improving visual acuity between ready-made spectacles and custom spectacles interventions in Myanmar. To the best of our knowledge, this study of this nature has not been conducted in Myanmar. In a low-resource country like Myanmar, the development of school-based vision care programs with the provision of affordable, accessible, feasible, and visual functionally improvable spectacles will be beneficial to school children with RE. The research hypothesis to be tested is that ready-made spectacle intervention is not inferior to custom spectacle interventions in improving visual acuity.

II. METHODOLOGY

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Methods:

2.1 Study design

This is a non- Inferiority Double Blind Randomized Clinical Trial to determine the effectiveness of ready-made spectacle as interventions and the custom spectacle as control and in improving visual acuity among school children in Yangon Region, Myanmar.

2.2 Settings and study population

We will recruit primary, middle, and high school students (from Grade 3 to Grade 10) from one urban township in Yangon, Myanmar to involve in the study. Inclusion criteria are school children of both sexes aged between 8 and 16 years with at least -0.50 D (20/40 in Snellen's Chart) and <-4.0 D, i.e. 20/300 in Snellen's Chart) of myopia. Those aged less than 8 years or over 16 years with significant RE, best VA<2 lines in both eyes (<20/40), reduced VA, not for URE, further examination required, with ≥2.00 D astigmatism, ≥2 D myopic anisometropia (the condition in which the two eyes have unequal refractive power), and ≥1 D hyperopic anisometropia and ocular disease affecting vision will be excluded from the study.

2.3 Sample size determination

The total minimum required sample is 250 to complete in each arm to be able to measure a 1% difference, assumed percent 'visual acuity' in the CS group with 80% and assumed percent 'visual acuity' in the RMS group with 79%. If there is a true difference in visual acuity, to be 80% sure that the upper limit of a one-sided 95% confidence interval will exclude a difference in favor of the CS group of more than the non-inferiority limit 10%. The alpha error is considered as 0.1 with 80% power.

Since there has been no previous study relating RMS and CS to improvement in visual acuity and cost effectiveness, especially in the Myanmar context, the following assumptions have been made. In the RMS group, the incremental power of the RMS is 0.25 diopters and many resource-poor countries have utilized this increment to limit its inventory and as such many children will have spectacle powers not falling within its increment. The assumption, therefore, is that only 79% of children will have VA Snellen 20/20. In the CS group, although the correct prescription in diopters may be provided, the optical technician in the optical shop in close proximity to the school may not be able to provide accurate spectacle power as per the prescription. As such, the assumption is that only 80% of the children will have VA, Snellen 20/20.

2.4 Sampling Procedure

Multi-stage sampling was used. In stage 1, a list of all townships was initially made along with their estimated population size in the Yangon region. Urban and rural population sizes are listed separately for each township. Townships that have more than 50% of their population are classified as urban townships. Using simple random sampling, two urban townships in the Yangon Region were selected. Stage 2 was the selection of public schools within each township. In each township, all public schools with student lists within these townships are recorded to be used as a sampling frame. Using simple random sampling, schools were selected to recruit approximately 5000 to 6000 school children for vision screening, assuming that 24.5% of school children had myopia[19]. Stage 3 involved random selection of children to participate in the survey. A list of all students and their ages were obtained by the study team. Each and every student who gives informed consent will be screened for their vision. From the eligible participants, simple random sampling was used to get the required sample size of 500. A replacement was selected through simple random sampling of the selected students who were not available. If any student refused to participate, then a replacement was selected through simple random sampling. During the recruitment process, all children requiring spectacles, whether eligible for the trial or not, were allowed to select the frames they preferred from a range of colored plastic or metallic frames.

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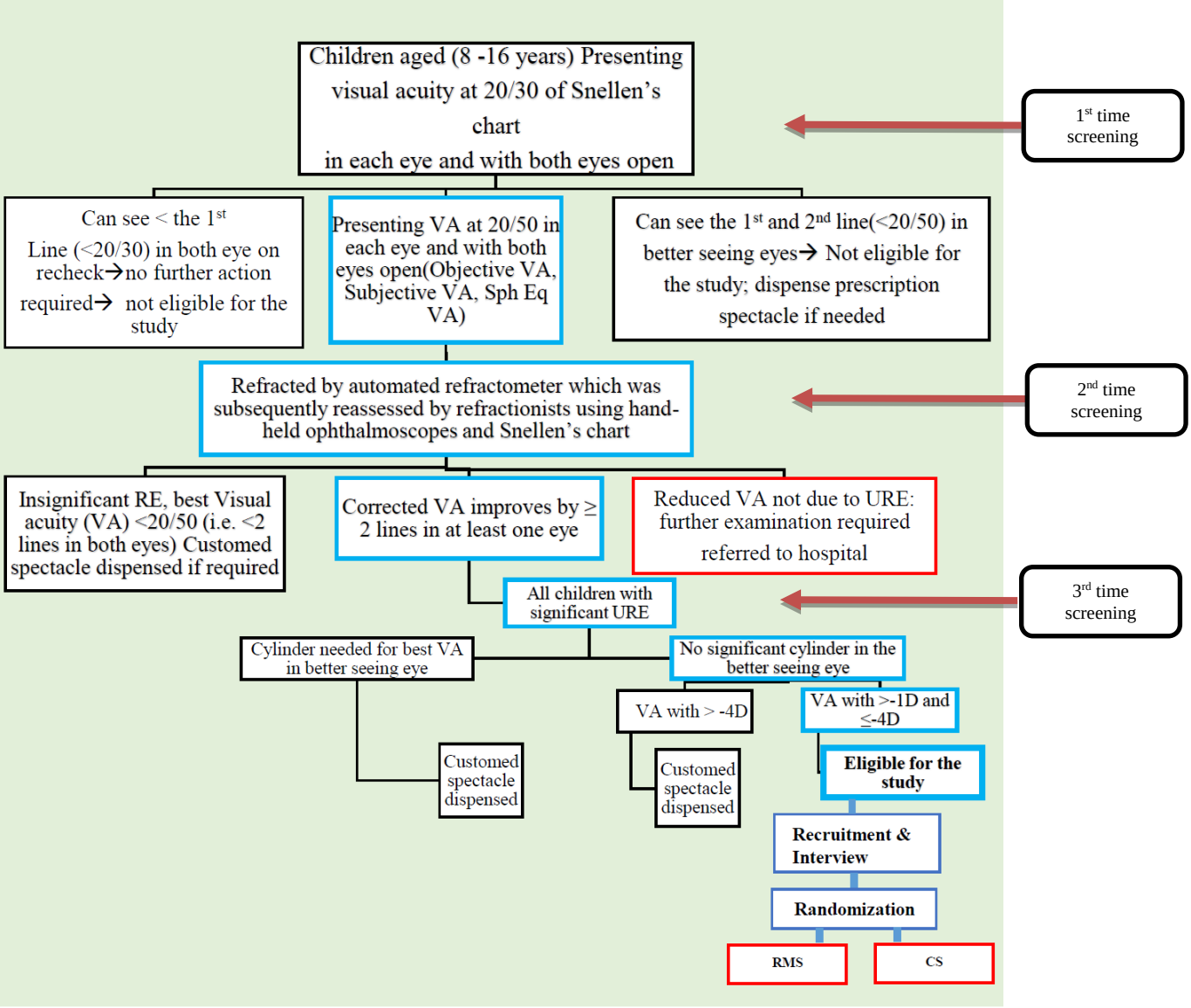

Figure 1 Randomization flow chart to show recruitment process for eligible participants and randomization

The flow chart in Figure 1 shows the activities involved from screening to deciding whether school children are eligible for recruitment. In the schools selected for the trial, trained teachers are going to measure visual acuity at the 20/30 level in each eye and with both eyes open, with spectacles if the child usually wears them. Snellen's chart will be used at the recommended test distance of 20 feet. School children who pass the screening test will be excluded from the study.

All children who present with visual acuity at 20/30 of Snellen's chart in each eye with both eyes open will continue to undergo a second time screening of both objective and subjective refraction by the refractionists. School children who have insignificant RE (better VA <20/50 or <2 lines in both eyes) will be excluded from the study after dispensing the custom spectacle if required. School children with reduced VA, which is not due to URE, will be referred to Yangon Eye Hospital for further examination.

Only school children who have corrected VA improvement by ≥ 2 lines in at least one eye will continue to undergo third time screening. School children who have a cylinder for the best VA in a better seeing eye will be excluded from the study after dispensing the custom spectacle. School children with no significant cylinder in the better-seeing eye, but VA with > -4D, they will also be excluded from the study after dispensing the custom spectacle. Only school children with VA between >-1D and ≤-4D will be eligible for the study.

Randomization (Block randomization)

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A consent form will be given to eligible children to be signed by their parents and return to the school. After recruitment, block randomization will be conducted to ensure a balance between treatment groups, in "blocks size of four" with each block having equal numbers of ready-made spectacle group (A) and custom spectacle group (B) in a ratio of 1:1. All possible six block permutations will be AABB, ABBA, BBAA, BAAB, ABAB, and BABA. A block will be chosen at random and treatments will be allocated accordingly. Allocation concealment will be obtained by using the random allocation sequence by block randomization, which will be conducted solely by the principal investigator (PI). No other person except PI will not be accessible to information regarding enrollment of participants, allocation sequence, and assignment of participants.

Masking

At the study site, PI will be the only person who will select envelopes that contain block assignment randomly. No other person except PI will be inaccessible to ensure allocation concealment. All school children and refractionists who will administer the interventions will be blinded to the group assignment in order to be double blind. Those recruited to the study will receive either RMS or CS free of charge. Participants will then be evaluated when they receive their spectacles and after 1 month of wear (Figure 2).

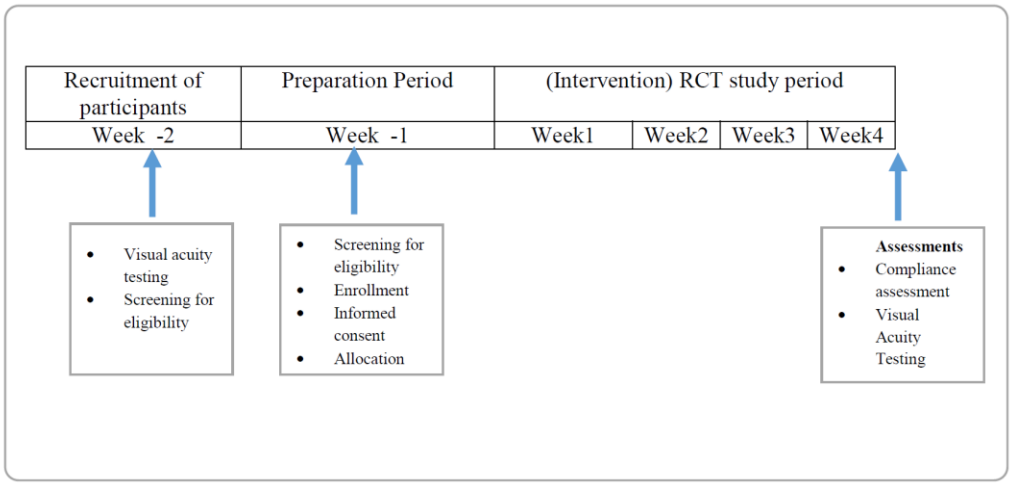

Figure 2 The schedule of enrolment, interventions, and assessments

2.5 Data collection methods and tools

Visual acuity measurement and data collection: At the start of the trial, a qualified refractionist or optometrist will measure visual acuity using objective refraction by retinoscopy, and auto-refractor and subjective refraction using loose trial lenses under the close supervision of an ophthalmologist. For the participants, having own spectacles will be rechecked prior to receiving the study spectacles. Visual acuity is measured using the foot (fractional) in Snellen's chart of 20/20 scale, and then converts to LogMAR scale to get continuous variables using a conversion table[20]. RE scores will be recorded in the participant's record. Then, the enumerator will record the score after asking a short survey, using a set of pre-coded questions in the KoBo collect toolkit. Record sheets will then be uploaded and the PI will check for their completeness and accuracy. To reduce inter-observer variation as low as possible, inter-observer agreement between refractionist in visual acuity testing and refraction will be evaluated through test-retest measurements during the training period. Standardization of clinical methods and procedures for refractionist is an important part of training. Data collection survey team will consist of three qualified refractionists, two trained enumerators, an ophthalmologist, and a team leader.

Spectacles prescription:

i. For the trial group, the spectacle lenses used in the RMS group will be −0.50 D to −4.0 D in 0.25 steps and have the same power in each eye.
ii. For the comparator group, the spectacle lenses used in the CS group are the exact power resulting from visual acuity testing by refractionists for each child.

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The researcher will provide all the cost of procurement of both RMS and CS spectacles that will be ordered from the optical store to get the exact power of the participants. The spectacles will be fitted by the refractionist and dispensed by the researcher in a subsequent visit to the school for those participants receiving either RMS or CS.

Visual outcome measurement at the end of the trial: Corrected vision will be measured with the study spectacles. After the spectacles have been fitted and dispensed, they will be followed up after one month. Outcomes are measured at the start date of the intervention pre- intervention and within one week after the intervention for post-intervention.

The primary outcome is compliance to the provided spectacles. We will access the proportion of children who are wearing spectacles at an unannounced visit to the school 1 month after the spectacle dispensing. A field worker, masked to the allocation arm, assesses spectacle wear and categorize whether wearing the spectacles at the time of the visit, not wearing the spectacles at the time of the visit but have them at school, not wearing the spectacles at the time of the visit but said they are at home, and not wearing the spectacles due to loss or broken.

The secondary outcome is the visual acuity in both the RMS and CS assigned children. In both groups it is determined for children with 20/20 (best corrected visual acuity) and those children with 20/25 (acceptable visual acuity) using Snellen's Charts. They are regarded as those with normal vision. Line read on the Snellen's chart by better seeing eye are noted and converted to the LogMAR Scale by the score conversion table described above[21]. For both groups for measuring visual acuity, both auto refractor and trial lenses will be used for measurement of VA (Table 1).

Table 1 Outcome variables and measuring instruments/ procedure

Outcome variable	Measuring Instrument/ procedure
compliance to the provided spectacles	Using the follow-up data collection form, the field worker asks the child the reason and this is coded and recorded.
Visual acuity	Using both auto refractor and trial lenses, the refractionsits will record the line read on the Snellen's chart by better seeing eye are noted and converted to the LogMAR Scale by the score conversion table.
Visual acuity improvement	Difference in visual acuity before and after wearing of spectacles in both groups

2.6 Data management and analysis

All refractionists have been trained, including inter-observer agreement studies for visual acuity measurement and refraction, all enumerators for data recording. Using password protected databases in Excel, all the data resulted from the KoBo collect will be entered. Data management team will keep recording forms and the data with the high concern of safety during the trial. Microsoft Excel 2016 will be used for data entry and the generation of graphs. STATA version 15 will be used for all statistical analysis. To have comparability of the intervention and control groups, characteristics of participant will be compared by sociodemographic characteristics, degree of uncorrected refractive errors, and presenting visual acuity in the better eye. Baseline data will be fitted in an analysis of covariance(ANCOVA). The randomization code will only be removed after analyzing all the data. 95% two-sided confidence intervals will be used for statistical uncertainties. A *p*-value of <0.05 will indicate statistical significance.

Data monitoring

Monitoring committee for data will not be necessary because both arms are non-invasive and not novel procedures but are in common use in daily practice. Significant adverse effects are not expected. As interim and subgroup analyses are not planned in the protocol, there will be no stopping rules.

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Protocol amendment

No important protocol modifications, such as changes to eligibility criteria, were required.

Ethical consideration

This randomized controlled trial will ensure; free and independent choice of the participant without coercion, provision of informed consent of the participants, maximum benefit with minimum risk, equal opportunity for all to participate in the trial, and no therapeutic misconception in the mind of the participants. The study will be conducted in accordance with the principles put forward in the Declaration of Helsinki in its current version.

Harms

In order to prevent harmfulness to the participants, it will be ensured to prescribe accurately to fitting of spectacles as unfitted spectacle can cause blurred vision and symptoms of eyestrain or headache. All refractions in this trial will be operated and prescribed by highly experienced and qualified refractionists. School children who have refractive errors but not suitable for ready-made spectacles are not eligible for the trial, thus, harm resulting from under or over correction will be reduced. Any child who says that blurred vision, eyestrain or headaches after wearing the prescribed spectacles will be refracted again and given a new pair of spectacles, if necessary. The study presents no additional risks to participants beyond those posed by assessment of visual acuity for RE.

Informed consent of Individuals

All participants will be required to give their written consent before they are enrolled into the study. As part of the informed consent process, the purpose of the study and all study procedures will be explained to them. All participants will have the right to withdraw from the study at any moment, without jeopardizing their access to any services.

Risks to Confidentiality

The following risks are associated with a potential breach of confidentiality: social risk due to stigma or other negative social outcomes of breach of confidentiality. There are other potential minor risks and concerns associated with participation in this study, including: inconvenience when the interview is taking longer than expected to administer; emotional or psychological effects if the topics of the interview arouse negative emotions, given the potential sensitivity of the issues to be studied.

To limit potential risks, participants will be informed as per the assent form that they can choose to not respond to any of the interviewer's questions and will be allowed to cease the study at any time. Participants will be provided contact information for the study by Principal Investigator, who will be available to answer any questions about the study at the conclusion of the interview process. All data will be de-identified on entry into electronic files, and personal identifying information will be removed from paper survey forms once data has been transferred to electronic files. A unique identifier code will be created to link the paper copies of completed surveys to each case in the electronic files, in case there is the need for verification during the data cleaning and analysis process.

Data Sharing

The Principal Investigators' role will be to ensure that the project is conducted as per the protocol and consistent adherence to operational procedures. The research will be monitored by the Principal Investigator(PI)and Co PIs. The results of the study will be made widely available in Myanmar. It will serve to inform the eye health practitioner community, those engaged in policy development at the Ministry of Health and Sports, academics working in the field of eye health in Myanmar, and an international community of interest. PI will hold a series of dissemination events to publicize the findings and be active partners in discussions about their implications for improving eye health services for school-aged children in Myanmar.

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Trial status

Recruitment was ongoing at the time of submission. Recruitment has been started on August 2020.

III. RESULTS

The proposal of this study was submitted to the board of studies and ethical approval has been received from the Institutional Review Board (IRB) of the University of Public Health, Yangon. It is also registered by Preliminary Registration: PLRID-00565_V1 at Myanmar Health Research Registry, Department of Medical Research, Yangon, The Republic of the Union of Myanmar. The trial will be conducted in August 2020, expected to be completed by September 2020. Final report will be submitted by December 2020.Trial registration data is described (table2).

I. Table 2. Trial Registration Data

Table 2 Data category and information of the trial

Data category	Information
Registry and trial identification number	**PLRID-00565_V1**
Protocol version	First version (June 9, 2020). No important protocol modifications, such as changes to eligibility criteria, were required.
Date of registration	1 February, 2020
Source(s) of monetary or material support	Ministry of Health and Sports, The Republic of Union of Myanmar
Primary sponsor	Implementation Research Grant of Ministry of Health and Sports, The Republic of Union of Myanmar
Contact for scientific queries	Soe Min Oo, MB,BS, MPH, MS Epidemiology, Department of Sports and Physical Education, Ministry of Health and Sports, Myanmar
Public Title	The effectiveness of the custom spectacle and ready-made spectacle interventions in improving visual acuity
Scientific Title	The effectiveness of the custom spectacle and ready-made spectacle interventions in improving visual acuity - non- Inferiority, Double Blind, Randomized Clinical Trial
Country of recruitment	Myanmar
Health condition(s) or problem(s) studied	Vision Impairment
Intervention	Ready-made spectacle provision as trial and custom spectacle as comparator
Key inclusion and exclusion criteria	Inclusion criteria: School students aged 8 to 16 years of both sexes from one urban township in Yangon, with visual acuity -0.50 D to <-4.0 D of myopia. Exclusion criteria: aged < 8 years or >16 years with significant RE, best VA<2 lines in both eyes, reduced VA, not due to URE, further examination required, with ≥2.00 D astigmatism, ≥2 D myopic anisometropia, and ≥1 D hyperopic anisometropia and ocular disease affecting vision.
Study Type	Interventional
	Allocation- non- inferiority, Double Blind, Masking, Randomized
	Primary purpose: Prevention
Date of first enrolment	1 August, 2020
Target sample size	500
Recruitment status	Recruiting
Primary outcome(s)	compliance to the provided spectacles
Key secondary outcomes	Visual acuity, visual acuity improvement

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IV. DISCUSSION

This trial is designed to explore whether ready-made spectacles are not inferior to compliance of spectacle wearing and improvement of visual acuity compared to custom spectacles. The findings of the study will disseminate to all the policy makers from the Ministry of Education and the Ministry of Health and Sports for the development of school-based eye health care programs and strategies to mitigate the burden of refractive error among students in Myanmar.

V. ACKNOWLEDGEMENT

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