

Development and validation of a new vision screening test algorithm for public use mobile application- A pilot study

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ABSTRACT

Objectives: To design and develop a simple vision test algorithm for mobile application and perform a pilot study to determine its validity and reliability as a tool for vision test in the community.

Methods: A simple visual acuity test algorithm in the form of a single letter E display was designed as the optotype for development of a mobile application. The standardised optotype is presented at random to test visual acuity for corresponding level of 3/60, 6/60, 6/18, and 6/12. The final result is auto-generated based on the classification of the WHO for visual impairment and blindness. The Snellen chart was used as the gold standard to determine its validity while five different users were involved to determine its inter-rater reliability. A pilot study was performed between April till November 2019, in the Universiti Sultan Zainal Abidin Medical Centre (UMC) at Kuala Nerus and Mooris Optometrist Centre at Marang, Terengganu. A total of 279 participants aged four years old and above were involved in this study.

Results: The highest sensitivity was found at the vision level cut-off point of 6/12 with the percentage of 92.7% and 86.8% for the right and left eye, respectively. The specificity was more than 89% for all vision levels in both eyes. The Krippendorff's alpha value for the inter-rater reliability was 0.87 and 0.83.

Conclusion: The relatively high level of validity and reliability obtained indicate the feasibility of using the designed optotype to develop a valid and reliable mobile app for vision test. The app can be used to screen vision by non-medical persons, at anytime and anywhere to help improve public awareness and capability to correctly determine their visual status.

KEYWORDS:

mobile application, vision screening, visual acuity, visual impairment, blindness

INTRODUCTION

Our eyes are the organ of vision, which gives an essential input to the human sensory system. In clinical practice, the assessment of the visual acuity status is a necessary routine test before any eye examination. All eye care practitioners require this critical information to anticipate the presence of

any ocular abnormalities or refractive error. Indeed, a regular eye examination and vision testing, starting from infancy, will significantly contribute to timely and appropriate management of all ocular disorders to prevent blindness.¹ The 2019 Vision Report of the World Health Organization (WHO) estimated about 2.2 billion people worldwide, or nearly one-third of the present world's population, are either visually impaired or blind. Remarkably, over one billion of the visually impaired and blind people around the world remain caused by avoidable conditions or unaddressed issues.² Even though some countries have reported a satisfactory level of awareness on eye diseases among their citizens, the necessities for early detection and proper treatment of any eye problems remains the priority.^{3,4}

One of the primary strategies of the WHO to lessen the number of avoidable, visually impaired and blind people is by improving the utilization and provision of eye care services via the innovations in health care technology.⁵ The current system of incorporating the use of technology in mobile devices by the health care sector is known as the mobile health or m-health system. The continuously emerging use of m-health aid in empowering the health care system is increasing, especially in the developing countries.⁶ Economically, the widespread use of the m-health system itself provides extra advantages by the improvement in communication between practitioners and patients, as well as in the service delivery system.^{7,8}

Therefore, for the crucial requirement to promote good vision and overcome the barriers towards seeking early treatment for any problems related to vision, we plan to develop a valid and reliable mobile application (app) for the vision screening test in the community. This is our primary objective of this study. We have also undertaken to develop the mobile app and provide the evidence and justification for the further development, promotion and usage of our proposed vision test app which is valid and reliable as a vision screening tool in the community.

MATERIALS AND METHODS

The initial idea, design, and development of the prototype for the future mobile app began in June 2018. Subsequently, a cross-sectional study for initial validation of the prototype was done. This study involved a total of 279 participants, where 161 were in the validity arm of the study and the other 118 for the reliability study. The study sites included the eye

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clinic of the Universiti Sultan Zainal Abidin Medical Center (UMC) in Kuala Nerus and the Mooris Optometrist Vision Care Center in Marang, Terengganu in Malaysia. The study period was between April and November 2019. The minimum age for all the subjects who had volunteered to participate were 4 years old and above. They were attendees of the two designated eye care and vision centres. Youngest participants of the four years olds were included so as to test the applicability of the mobile app and to represent the preschool children in Malaysia, although some studies have reported the involvement of children as early as three years old among their group of preschoolers.⁹⁻¹¹ The inclusion criteria of participants in both validity and reliability arms were as follow; those who were able to communicate, of reliable mental status and physically able to perform the vision test. Minors without a rightful guardian and those in pain or need of any emergency care were excluded (Figure 1).

The currently available vision test charts use multiple optotypes in many different forms of letters, numbers, or pictures for the assessment and monitoring of distance visual acuity in daily clinical practice. The most current practice for the assessment of distance visual acuity utilises either the Snellen or the Early Treatment for Diabetic Retinopathy Study (ETDRS) vision test charts. Until now, there have been many debates and disputes comparing these two charts regarding the standardisation and the accuracy of their visual acuity findings.¹²⁻¹⁴ Although numerous clinical publications have described the advantages of visual acuity assessment in the non-Snellen form,¹⁵ the use of Snellen fraction to express the visual acuity scoring is still widely used by most practitioners. Thus, the right selection of vision test chart will provide the most suitable, valid and cost-effective screening tool.

We decided to use the single letter E as the optotype for our app because of the familiarity of the Tumbling E optotype present in both the Snellen and ETDRS charts. Many studies, with objectives of determining the prevalence of visual impairment and blindness, have utilized the Tumbling E charts for their visual acuity assessment in their survey.^{16,17} The Tumbling E chart is easy to understand and use, and moreover has a more significant advantage for the illiterates. Even preschool children continue to show high agreement in studies that utilized the Tumbling E chart against any other validated pediatric vision charts.¹⁸

Bearing in mind the presence of flaws in the Snellen chart testing, we chose to incorporate the ETDRS design principles in our vision test algorithm. However, our app still uses the Snellen fraction to be able to generate the results according to the most current and easily understood WHO classification of visual impairment and blindness. The WHO definition for blindness is when the presenting visual acuity is worse than 3/60; severe visual impairment is when the presenting visual acuity is worse than 6/60 but better than or equal to 3/60; moderate visual impairment is when the presenting visual acuity is worse than 6/18 but better than or equal to 6/60; and; mild visual impairment is when the presenting visual acuity is worse than 6/12 but better than or equal to 6/18.²

The construction of the optotype for our future mobile app follows several guidelines to ensure standardisation of the size of letter E presented, is proportionate to the size of the actual ETDRS and Snellen charts at the selected visual acuity levels. We decided to test for four levels of visual acuity i.e., 3/60, 6/60, 6/18, and 6/12. According to the principles of Snellen chart acuity, individuals with normal recognition acuity are capable of resolving an optotype with a visual angle of 5 minutes of arc and resolution angle per letter stroke of 1 minute of arc.²⁰ Given that the different alphabets used in the Snellen letters have various sizes and may lack readability for the minors and illiterate, the letter E in a 5 x 5 grid for its height and width similar with the Sloan letters or Tumbling E used in the ETDRS chart, is the best alternative.²¹ Thus, we expect the participants to encounter the same level of difficulty as the actual ETDRS chart when viewing the letter E, at the selected visual levels displayed by the mobile devices (Table I). Following the guidelines for vision chart design, a black over a white background used for the letter E will provide the maximum contrast of over 80% for its optotype.²⁰

Only four levels of visual acuity are selected based on the classification of visual impairment and blindness by WHO i.e., 3/60, 6/60, 6/18 and 6/12. Owing to the small and different sizes of the screen for all available models of mobile phones and smart devices, we could display only one letter at one time from the testing distance of 1.5 and 3 meters (Figure 3). Thus, the app will present the letter E in one out of the four directions (0°, 90°, 180°, or 270°) in a random manner to avoid bias or memorization. A participant need to point out the direction of the letter E, and the examiner will swipe the screen in the same direction indicated by the participant accordingly. Every level of visual acuity tested will repeatedly display the letter for a maximum of five times. The test will continue to the next level of vision when the participant achieves three correct answers and will end automatically after three wrong answers given. However, in circumstance when the participant fails to pass at any of the visual levels, he or she needs to put on a single pinhole aperture of approximately 1 to 2mm in size while viewing the optotype in the subsequent vision test. Finally, the vision test results will be auto-generated according to the WHO classification of visual impairment and blindness.

To validate the app, the standard Snellen chart presented from the testing distance of 6 metres was used as the gold standard for this study. The validity is determined by its sensitivity and specificity level, along with the positive and negative predictive values, to indicate the performance of the future app as a screening tool. In order to suit with the multiple categories of the data presented in this study, marginal homogeneity statistical analysis is used to determine the validity.²² Meanwhile, repeating the use of the prototype for the vision test on the same participant by 5 different examiners will determine its inter-rater reliability or consistency (Figure 1). Given the categorical nature of the data produced were according to the five categories of vision levels identified by 5 different users, Krippendorff's alpha statistic was considered as the most appropriate statistical analysis for the reliability determination,^{23,24} by using the Stata statistical software (StataCorp LP. 2017, Release 15. College Station, TX). This validation study obtained its

Table I: Calculated letter size for mobile app prototype and Snellen chart

Visual level (Snellen fraction)	Mobile app prototype			Conventional Snellen		
	Testing distance (meter)	Optotype E height (mm)	Optotype E width (mm)	Testing distance (meter)	Optotype height (mm)	Optotype width (mm)
3/60	1.5	44.0	44.0	3.0	42.8	42.8
6/60	3.0	44.0	44.0	6.0	87.5	87.5
6/18	3.0	13.0	13.0	6.0	26.2	26.2
6/12	3.0	8.5	8.5	6.0	17.5	17.5

Legend: Calculated letter size of conventional Snellen are based on the Sloan letters with 5x5 grid

Table II: Summary of the diagnostic test results for the mobile app against the gold standard, the Snellen chart for vision of the right eye (VR) and vision of the left eye (VL)

Vision test	Visual acuity level cut-off (VA worse than)	Sn (95% CI)	Sp (95% CI)	PPV (95% CI)	NPV (95% CI)
VR	6/12	92.7% (88.6, 96.7)	91.4% (87.1, 95.7)	88.7% (83.6, 93.6)	94.9% (90.9, 98.0)
	6/18	73.8% (67.0, 80.6)	98.0% (95.8, 100.0)	95.7% (92.6, 98.9)	86.0% (80.6, 91.3)
	6/60	53.3% (45.6, 61.0)	99.3% (98.0, 100.0)	88.9% (84.0, 93.7)	95.4% (92.2, 98.6)
	3/60	20.0% (13.8, 26.2)	99.4% (98.1, 100.0)	50.0% (42.3, 57.7)	97.5% (95.07, 99.9)
VL	6/12	86.7% (81.5, 92.0)	89.3% (84.5, 94.0)	85.5% (80.1, 90.9)	90.2% (85.6, 94.8)
	6/18	83.6% (77.9, 89.4)	93.4% (89.6, 97.2)	86.8% (81.6, 92.0)	91.7% (87.4, 95.9)
	6/60	50.0% (42.3, 57.7)	96.6% (94.0, 99.4)	54.6% (46.9, 62.2)	96.0% (93.0, 99.0)
	3/60	0.0% (0.0, 0.0)	99.3% (98.1, 100.0)	0.0% (0.0, 0.0)	94.4% (90.8, 97.9)

Legend: VR - Vision Right, VL - Vision Left, VA - Visual acuity, Sn - Sensitivity, Sp - Specificity, PPV - Positive Predictive Value, NPV - Negative Predictive Value

ethical approval from the Universiti Sultan Zainal Abidin Human Research Ethics Committee (UHREC) with the reference number UniSZA.C/2/UHREC/628-2 Jld 2 (8) dated 12th September 2019.

RESULTS

From a total of 161 participants in the validity arm of the study group, 72% from them were females. The mean age was 30.9±15.9 years; the minimum was 8, and the maximum was 79 years. The vision test results revealed a high level of sensitivity for diagnosing visual impairment worse than 6/12 in both the right and left eye of the participants at 92.7% and 86.7%, respectively (Table II). In other words, it indicated that the app is good at detecting eyes with visual impairment or ruling out those eyes with normal vision. Besides, the vision test had a high specificity level of more than 89% in all categories of visual impairments. It indicated its excellent capability of detecting or ruling in cases at all levels of visual impairment and blindness, with the specificity level ranging from 89.3% to 99.4% (Table II).

For the right eye, the positive predictive values (PPV) varied from moderate to high percentages, with the highest at 95.7% for positively detecting vision worse than 6/18. The PPV for the left eye was lower than the right, which ranged from 0.0% to 86.8%. The negative predictive value (NPV) for the right eye ranged from 86.0% to 95.7%, while the NPV

obtained for the left eye for all vision levels was more than 90% (Table II).

Among the total of 118 participants in the reliability study group, 58.5% of them were males. The mean age was 30.5±20.2 years, the minimum was 4, and the maximum was 68 years. The inter-rater vision test revealed a reliability index at a satisfactory level with the Krippendorff's alpha values of 0.87 and 0.83 for the right and left eye, respectively.

DISCUSSION

Any disorders in the visual system which disrupts the attainment of a normal vision will affect the performance of individuals in their vision test, and subsequently in their daily activities. Many previous studies have elaborately addressed the need for early detection of visual impairment. Timely referral and appropriate treatment can help in avoiding further vision loss and thus improving the quality of life.²⁵ With the significant numbers of people with unaddressed and preventable visual impairments and blindness in the world, it is crucial to promote the importance of monitoring and maintaining healthy vision.²

As a part of the WHO agenda to reduce the number of avoidable blindness cases worldwide, various national and international authorities have implemented remarkable efforts to address this issue till the present day. The

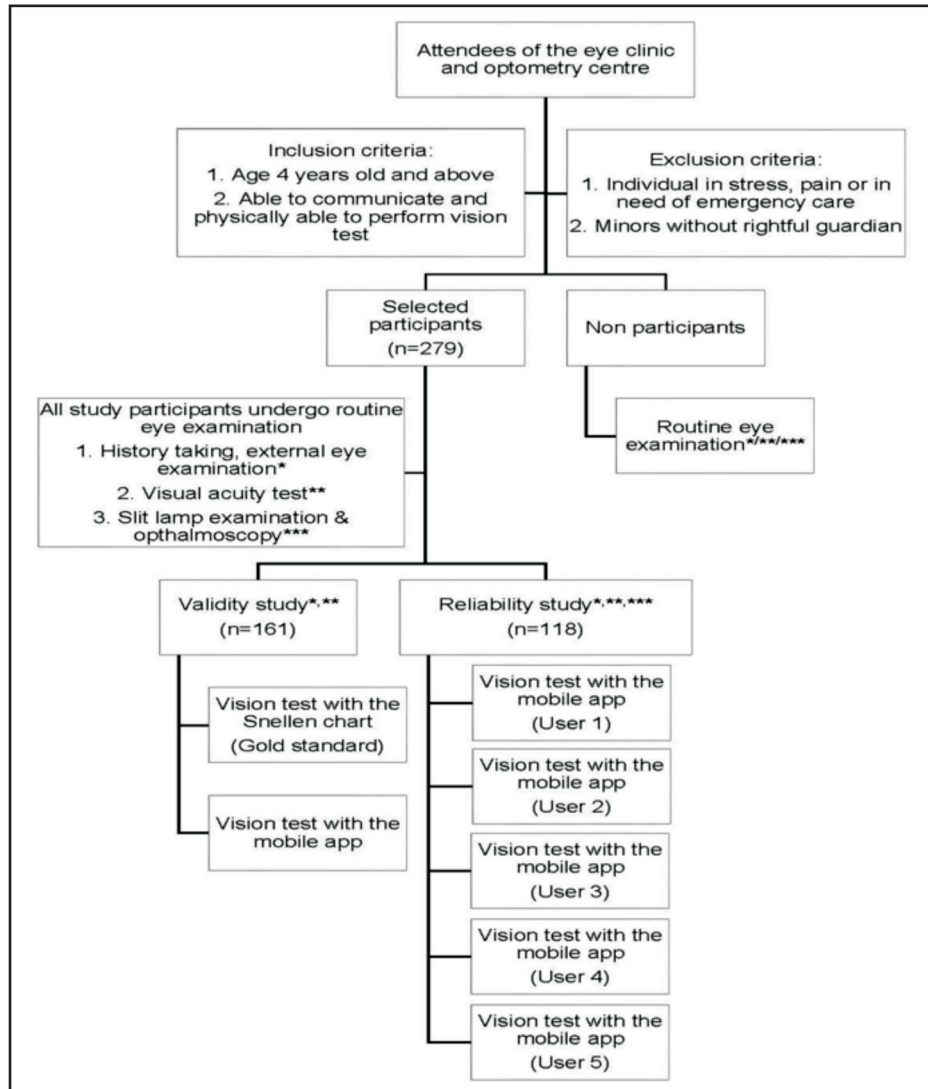


Fig. 1: The study flowchart for validity and reliability determination.

Legend: Data for the validity arm was taken at Mooris Optometrist Vision Care Center, while UniSZA Medical Center (UMC) was the site for the reliability arm

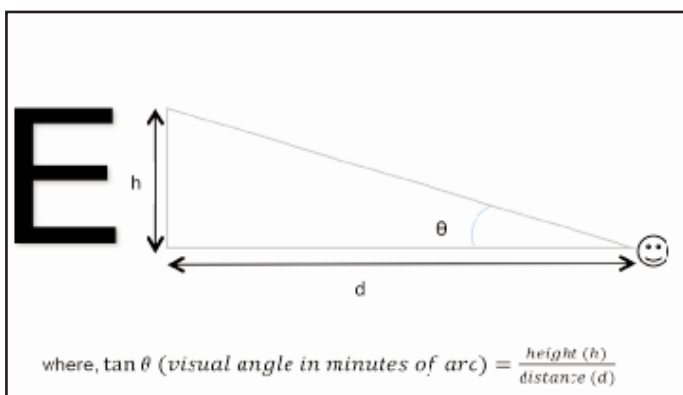


Fig. 2: Illustration for Snellen visual acuity letter size.

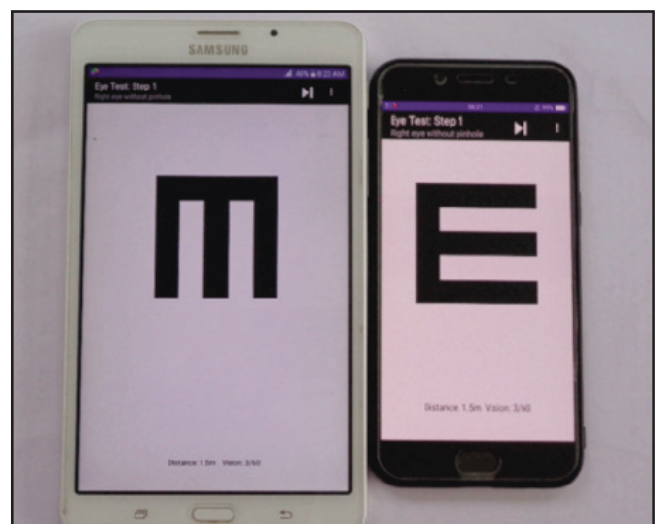


Fig. 3: The optotype for similar level of vision test displayed by two different sizes of mobile devices; mobile tablet (left) and android smartphone (right).

introduction and propagation of modern and digital technology in mobile devices is another practical approach in the effort to achieve these goals. For visual acuity assessment, some mobile apps are readily available to aid the health and eye care practitioners in their clinical practice. The initiatives to introduce the portable-type visual acuity assessment tools or mobile apps with the use of smart devices have steadily emerged since 2012. The Eye Snellen, Eye Chart Pro, Rapid Eye Screening Test (REST), Peek Acuity, and Vision at Home (V@Home) are some examples of the mobile apps produced since then. However, most of the apps still lack evidence regarding the validity of their vision test results. Therefore, serious issues might arise in terms of the possibility of obtaining misleading results. From the available apps, Peek Acuity is an example of a validated app, and it is presently the only one recognised and endorsed by the WHO to be used for vision screening purposes.²⁶

In the initial effort to validate our prototype, the diagnostic tests performed has shown promising results. The highest level of sensitivity level obtained was at the cut-off point level of 6/12, in order to detect the presence of visual impairment worse than 6/12 or rule out individuals with normal vision. However, diminishing sensitivity level at the subsequent cut-off level, with the least data obtained to detect the blind, was due to the limited number of participants with severe visual impairment or blindness. The lower sensitivity level may also be indicative of the very low prevalence of severe visual impairment and blindness among the population selected to be involved in this pilot study. On the other hand, adequately high specificity level of more than 89% was obtained for both the right and left eye vision test to detect all levels of visual impairment. Regardless of the variations in the sensitivity levels obtained, the optotype design that we chose proved to be highly specific and is therefore highly capable of correctly identifying all participants with significant level visual impairment or blindness with vision worse than 6/12.

Comparatively, the Peek Acuity app was reported to have attained 85% sensitivity and 98% specificity to detect vision worse than 6/60 among the older people aged 55 and above.²⁶ In another study involving a group of primary school children between year 1 till 8, the Peek Acuity showed lower sensitivity of 77% and specificity of 91% for vision cut-off point at 6/12.²⁷ For our study, at the similar level of vision cut-off point of 6/12, our prototype showed an almost equal level of both sensitivity (92.7% and 86.7%) and specificity (91.4% and 89.3%). Hence, this indicated that our future mobile vision test app will be an equally valid and reliable tool for vision screening as the WHO recognised Peek Acuity app.

The PPV obtained in this study, ranged from 0.0% to 95.7% in both the right and left eye vision tests. The lowest PPV value of 0.0% was obtained in the left eye as none of the participants had vision worse than 3/60. Nevertheless, other PPV values of over 50.0% at all other vision levels for both eyes have indicated the fairly good capability of the app to detect almost all level of visual impairment. The NPV obtained were equally high in both eyes, with an average of more than 86% for every category of visual impairment and blindness. As these predictive values are strongly related to the prevalence of visual impairment and blindness,²⁸ the lesser percentage of PPV obtained might rightly reflect the

relatively lower prevalence of severe visual impairment and blindness in our population study group. In spite of the lower PPV, the relatively higher NPV for all vision levels indicates that our app has high enough accuracy to rule out participants with normal vision. This was a pilot study with smaller sample size, hence the subsequent full validation study will require a larger population and representative number of sample size.

In order to determine the consistency of the vision test results, we performed the inter-rater reliability test by recruiting 5 different users of the prototype using the same optotype, with similarly identical test algorithm and study protocol. The Krippendorff's alpha values of more than 0.83 obtained indicate a satisfactory level of agreement, thus promises a reliable future mobile vision test app. With the adequately high level of validity and reliability obtained by our prototype, it is thus highly encouraging to fully develop the mobile app for a vision screening test. Subsequently, the fully developed app will require further full validation study to provide the evidence for its future promotion and to secure the WHO's recognition.

For any visual acuity assessment, the practical use of the pinhole is apparently to limit the amount of light entering the eye. It helps to minimise the circle of blur formed on the retina, thus increase the depth of focus. Likewise, the concept was utilised in our app; therefore, clinical practitioners may be able to distinguish the potential cause of visual impairments either refractive errors or any ocular pathologies. At present, no other mobile apps offer a similar algorithm in their built-in vision test. Additionally, simple procedures and presented results displayed by our prototype app can help any person to understand and conduct the vision test correctly among themselves.

The vision test, which requires the preschool group of children to identify and name the letters, may be too difficult for the younger ones if compared to children in the older age group. Although there have been many debates on the suitability of the letter-type-based visual acuity assessment among preschool children, the capability to perform the test was noted to increase to 93% among them with the use of letter matching cards.²⁹ Nevertheless, the preschool children in our study were able to understand our letter E optotype, and they have managed to complete our vision test with a brief demonstration from the examiners before the procedure. In school children, the visual acuity for cut off referral commonly set at 6/9 as reported from many studies before. Though the visual acuity referral criteria differ between preschool and school-age children with the adult group, some studies still reported the use of 6/12 as the cut-off point in their study protocol. For instance, among the indigenous primary school children in Negeri Sembilan, visual acuity cut off referral of 6/12 conducted by the optometrists, was used to determine the prevalence of visual impairment among them.³⁰ A similar circumstance was also noted in Vietnam with the same cut-off point, performed by trained school teachers which was then repeated by refractionists.³¹

We need to bear in mind other limitations noted in this study to prepare for the future full validation study. The different

brand, models and the screen brightness of the mobile devices used by the examiners in this study were not specified or standardized to any level. Previous studies on the use of mobile devices in visual acuity assessment showed superior compliant of luminance and contrast in comparison with the retro-illuminated ETDRS chart. At 75% brightness setting, the standard luminance, luminance uniformity and contrast demonstrated by the mobile devices were optimized, thus fulfilled the requirement by British Standard recommendations.³² Even though there was no significant difference noted in visual acuity measurements reported between retro-illuminated and mobile device charts,³³ we should have advised our examiners to set the screen brightness from 75% to nearly maximum before beginning the vision testing. Additionally, our vision test was mostly performed in general areas without controlled-lighting to minimize glaring. This emulates the community environment where controlled-lighting might not be possible. Nevertheless, it is a good practice to ensure the outer field of the testing area is less bright than the testing area. Thus, a recommended level of luminance between 80 to 300 lux within the testing area could be proposed to avoid any influence of ambience luminance on the measurements taken in future.^{26,34}

CONCLUSION

This study indicates that the chosen design and randomly displayed optotype is adequately valid and reliable for our future mobile vision test app. It will be incorporated into our future mobile app to be developed as a vision screening tool which will provide anyone a simple and easy to perform vision test procedure by the public to correctly assess their current visual status, at anytime and anywhere.

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