Smartphone-based screening for visual impairment in Kenyan school children: a cluster randomised controlled trial

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Summary

Background Childhood visual impairment is a major public health concern that requires effective screening and early intervention. We investigated the effectiveness of Peek school eye health, a smartphone-based sight test and referral system (comprising Peek Acuity test, sight simulation referral cards, and short message service [SMS] reminders), versus standard care (Snellen’s Tumbling-E card and written referral).

Methods We initially compared the performance of both the Snellen Tumbling-E card and the Peek Acuity test to a standard backlit EDTRS LogMAR visual acuity test chart. We did a cluster randomised controlled trial to compare the Peek school eye health system with standard school screening care, delivered by school teachers. Schools in Trans Nzoia County, Kenya, were eligible if they did not have an active screening programme already in place. Schools were randomly allocated (1:1) to either the Peek school eye health screening and referral programme (Peek group) or the standard care screening and referral programme (standard group). In both groups, teachers tested vision of children in years 1–8. Pupils with visual impairment (defined as vision less than 6/12 in either eye) were referred to hospital for treatment. Referred children from the standard group received a written hospital referral letter. Participants and their teachers in the Peek group were shown their simulated sight on a smartphone and given a printout of this simulation with the same hospital details as the standard referral letter to present to their parent or guardian. They also received regular SMS reminders to attend the hospital. The primary outcome was the proportion of referred children who reported to hospital within 8 weeks of referral. Primary analysis was by intention to treat, with the intervention effect estimated using odds ratios. This trial is registered with Pan African Clinical Trial Registry, number PACTR201503001049236.

Findings Sensitivity was similar for the Peek test and the standard test (77% [95% CI 64–86·5] vs 75% [63·1–85·2]). Specificity was lower for the Peek test than the standard test (91% [95% CI 89·3–92·1] vs 97·4% [96·6–98·1]). Trial recruitment occurred between March 2, 2015, and March 13, 2015. Of the 295 eligible public primary schools in Trans Nzoia County, 50 schools were randomly selected and assigned to either the Peek group (n=25) or the standard group (n=25). 10 579 children were assessed for visual impairment in the Peek group and 10 284 children in the standard group. Visual impairment was identified in 531 (5%) of 10 579 children in the Peek group and 366 (4%) of 10 284 children in the standard group. The proportion of pupils identified as having visual impairment who attended their hospital referral was significantly higher in the Peek group (285 [54%] of 531) than in the standard group (82 [22%] of 366; odds ratio 7·35 [95% CI 3·49–15·47]; p<0·0001).

Interpretation The Peek school eye health system increased adherence to hospital referral for visual impairment assessment compared with the standard approach among school children. This indicates the potential of this technology package to improve uptake of services and provide real-time visibility of health service delivery to help target resources.

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Introduction

Worldwide, an estimated 19 million children have visual impairment (defined as Snellen visual acuity of <6/12 [or <20/40] in the better-seeing eye). Visual impairment can have a profound effect on child development, quality of life, educational attainment, and economic productivity.1,2 The leading cause of visual impairment in children is uncorrected refractive error, affecting approximately 12 million children, which can be easily corrected with spectacles.3 Many school children are held back by poor sight for lack of this simple intervention. Most children with visual impairment live in low-income countries.4 In Kenya, for example, the estimated prevalence of visual impairment among school children (6–20 years) ranges from 4·8% to 5·6%.5,6 In Asian populations, estimates range from 6·4% to 22·3%.7–9

Addressing childhood blindness and visual impairment is a major priority for VISION2020, a global programme fighting avoidable blindness led by WHO and the International Agency for Prevention of Blindness.8 To reduce childhood visual impairment, the programme promotes vision screening of all children who go to
Articles

Research in context

Evidence before this study
A systematic review of mobile health (mHealth) applications for vision testing identified numerous available applications; however, very few had undergone validation or certification. mHealth systems have shown promise for improving healthcare delivery although no trials of mHealth interventions to improve eye health have been published.

Added value of this study
This study showed both the feasibility of effective task-shifting to teachers using the Peek school eye health system to identify and refer children with sight problems and substantially increased adherence to referral (within 8 weeks of screening) of those identified by establishing a closed-loop between screeners (teachers) and the service provider (hospital).

Implications of all the available evidence
Poor vision has negative social, health, educational, and economic consequences. Early identification and treatment of eye conditions reduces the prevalence of visual impairment. Our results have shown that the Peek school eye health system, when used by teachers, is effective for identification and referral, as well as providing live health system data with evidence of barriers to service delivery. The lessons learned from this trial have been adopted and scaled up in Kenya by the Ministries of Health and Education to a countywide programme, serving 200,000 children. Additionally, this programme has been replicated and further developed in India and Botswana, which is taking it to a national scale.

Methods

Study design and participants
We first did a validation study to confirm that the teachers could be trained to carry out vision screening. We compared the performance of both the Snellen Tumbling-E card and the Peek Acuity test with a standard backlit EDTRS LogMAR Tumbling-E visual chart (Precision Vision, Woodstock, IL, USA) in measuring visual acuity in children. The order of the assessments was random. This validation study was carried out in three schools not involved in the subsequent trial.

We then did a single-masked, parallel-group, cluster randomised controlled trial in 50 primary schools in Trans Nzoia County, Kenya. Clusters were individual schools with no active visual screening programme in place. School children were tested for visual impairment by teachers who were trained to use either the standard school screening system Snellen Tumbling-E card and paper referral) or the Peek school eye health system. CONSORT guidelines for reporting cluster randomised trials were followed.9

All pupils attending years 1–8 in the selected schools were eligible for inclusion. Children were provided with information and consent forms to give to parents or guardians who were then requested to give written informed consent for teachers to test eye sight before enrolment. Children were excluded if they were unwilling or unable to give verbal consent, or if their parents or guardians did not provide consent.

school and promotes integration of vision screening into school health programmes by 2020. Vision testing to identify children with correctable visual impairment enables interventions to be offered early, before educational and social progress is adversely affected.10 Vision screening of children in Kenya is guided by school policies.11 In areas with active programmes, trained hospital-based clinical officers and ophthalmic nurses usually carry out the screening in schools. This procedure requires eye-care workers to leave their usual workplace (hospital eye clinics), thus reducing the availability of these services. In a pilot school-screening programme in Trans Nzoia County, Kenya, we trained school teachers to identify children with visual impairment using a Snellen Tumbling-E card. Children passed or failed at two predefined threshold levels: 6/60 (20/200) and 6/12 (20/40), in either eye. A hospital referral was made for children failing at either level by sending a letter to the child’s parent or guardian explaining the need to access care. However, only a few children attended this hospital referral. Multiple barriers to care include communication failure between pupils or schools and parents or carers, as well as between schools or carers and hospitals, the inaccessibility of services, direct and indirect costs, myths related to treatment, and fear.9

Access to a connected mobile device in sub-Saharan Africa has increased dramatically in recent years, from 1% in 2002 to around 75% in 2016.10,11 This increase in use is resulting in profound improvements in communication and commerce, and opens new opportunities for health care. Use of mobile health (mHealth) interventions to support communication between providers and patients through short messaging services (SMS) can promote access to health care.12 Previously, we developed and tested a smartphone application for Tumbling-E visual acuity testing (Peek Acuity app) to measure visual acuity in adults in Kenya. This test was accurate and repeatable, and acceptable to patients, examiners, and stakeholders.16,17 We have now integrated this app into an mHealth system for vision screening among school children. The aims of this study were to validate the Peek school eye health system and to assess the effect of this system on the referral rate of children with visual impairment compared with the standard visual screening system currently used in Kenya.
The study was approved by the Moi University Institutional Research and Ethics Committee, Kenya and the London School of Hygiene & Tropical Medicine Ethics Committee, UK. Permission was also granted by Trans Nzoia Education and Health authorities, Kenya. The study adhered to the principles of the Declaration of Helsinki on Ethics.

Randomisation and masking
Schools were randomly assigned (1:1) to either the Peek school eye health system (Peek group) or the standard school screening system (standard group). Geocoordinates of all eligible schools were obtained. To minimise imbalance in geographical location between the two groups, a statistician used a minimisation-based algorithm in R based on the geographical location (six zones, each covering 60 degrees of a circle around Kitale hospital) of the schools and their distance from the hospital, using random permuted blocks. Using this balance algorithm, we obtained a set of optimal allocations and sampled the final distribution of allocations from this set of optimal allocations.

We could not mask the study team providing training, or mask participants and teachers to the screening method being used. The primary outcome data were collected by one hospital clerk who was masked to the screening method used. On arrival at the hospital, the child’s parent or guardian presented a referral slip, which was identical for each group. Children who attended the hospital where a database of referred children was kept were shown a Tumbling-E vision screening card (figure 1A) at a distance of 3 m. This card has a row of five letter Es, in four different orientations. The size of the letters at this test distance corresponds to a visual acuity of 6/12. The child passed the 6/12 threshold test if they correctly identified the direction of four of the five letter Es. If they failed at 6/12, they were shown the 6/60 card, which has larger letter Es, and again passed if four of five were correctly identified. The result was recorded for each eye separately as: can see 6/12, cannot see 6/12 but sees 6/60, or cannot see 6/60. Children who could not see 6/12 in either eye were referred to Kitale hospital. The paper referral form was completed in triplicate: one copy given to the child, advising the parent to take the child to hospital, one copy to the head teacher, and one copy sent directly to the hospital.

In schools allocated to the Peek school eye health system, the teacher used the Peek Acuity vision screening app on a smartphone (Samsung Galaxy S3) at 2 m. Each eye was tested separately, with the fellow eye covered with an occluder. A series of up to five Tumbling-E optotypes equivalent in size to Snellen 6/12 (20/40, LogMar 0.3) were presented randomly in one of four orientations (figure 1B). The child pointed in the direction they perceived the arms of the letter E to be pointing, and the teacher used the phone’s touch screen to swipe in the same direction to enter the child’s response, without looking at the phone’s screen. One optotype was presented at a time. The test automatically concluded when the threshold number of passes (four of five) or fails (two of five) at the 6/12 optotype size was reached. If the child failed the 6/12 level, the app automatically presented a 6/60 sized optotype and the test was repeated to determine whether or not 6/60 (20/200, LogMAR 1.0) could be seen. At the end of the test, if the child failed the 6/12 level in either eye (ie, screened positive), the app prompted the collection of referral details (patient’s or guardian’s name, local language, and mobile phone number) and generated a referral to the hospital. A child who screened positive was given a printed referral photo card with their name, hospital contact details, and opening times to take home. The card included a split image with one half blurred to the same degree as the child’s visual impairment (figure 1C). When connected to the internet, the app sends this referral details to a cloud-based server, which automatically generated a personalised SMS that was then sent to the child’s parent or guardian with advice on the outcome of the eye assessment and instructions for referral in the chosen local language (figure 1D). A contact person (usually the head teacher for schools) also received an SMS with a list of children found to be visually impaired, needing referral. The messages were resent at intervals of 2 weeks until the child attended the hospital or for a maximum of 8 weeks. A referral was also automatically sent to the hospital where a database of referred children was kept accessible through a hospital reception app.

The follow-up period of this trial was 8 weeks. On presentation to the eye department at Kitale hospital for...
assessment, a clerk recorded the attendance of the referred child. The clinical team assessed the child to determine the level of vision, cause of visual impairment, and any treatment needed. Interventions included provision of eye drops, spectacles, or surgery. The team assessed visual acuity using a 6 m Snellen chart and classified the cause of vision loss on the basis of common treatable or preventable causes. All children with visual impairment received free treatment at hospital.

Outcomes
The primary outcome, which was centrally assessed, was the proportion of referred participants who attended the Kitale hospital eye department within 8 weeks of referral. The main secondary outcome was the time taken by children with visual impairment to reach hospital. We also report the level of vision measured in hospital and the causes of visual impairment identified.

Statistical analysis
We calculated the sample size assuming a visual impairment prevalence of 4.8% (<6/18 in better eye) and average school size of 542 pupils (about 25 visually impaired children per school). Assuming a design effect of 1.24 (ie, intraclass correlation coefficient 0.01) at least 21 schools were required in each group to provide 80% power to detect a difference of 10% (60% in the Peek group vs 50% in the standard group) in overall hospital attendance within 8 weeks. However, to ensure enough power would be retained to detect this difference if some schools dropped out of the study, we selected a final sample of 50 schools (25 in each group), providing 88% power to detect this difference if all schools participated.

For the initial validation study, we defined a child as visually impaired if they had at least one eye classed as having vision worse than 6/12 (or worse than 0.3 when using LogMAR). Using ETDRS LogMAR as the reference test, and the previous definition of visual impairment as the outcome, we estimated the sensitivity, specificity, positive predictive value, and negative predictive value for Peek and Tumbling-E cards.

The analysis was by intention to treat. For the primary outcome analysis, we used mixed effect logistic regression...
to estimate the odds ratio (OR), comparing the odds of attendance within 8 weeks of referral between the control (standard) and intervention (Peek) groups, first unadjusted and then, in case of any imbalance between demographics in the two groups, adjusted for age, sex, education level, and distance to hospital.

We generated Kaplan-Meier (K-M) survival curves to illustrate the difference in time-to-attendance between the two groups. We assessed the difference in time-to-attendance with hazard ratios (HRs) estimated by Cox regression, with a shared frailty at school level, first unadjusted and then adjusted for age, sex, education level, and distance to hospital. We checked Schoenfeld residuals and did a test of proportionality of hazards to identify if the assumption of proportional hazards was valid. In the case of the proportional hazards assumption being violated, we estimated HRs for narrower time bands, within which the proportional hazard assumption holds. We assessed the relationship between level of vision and diagnosis at hospital descriptively. We used STATA version 13 (STATA Corp, TX, USA) for the analysis.

The trial was registered with the Pan African Clinical Trial Registry, number PACTR201503001049236.

Role of the funding source
The funders of the study had no role in the study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results
In the validation study, we tested the visual acuity of 1862 children using Peek Acuity, the standard Tumbling-E card, and ETDRS LogMAR (the reference test). Prevalence of visual impairment, as measured by ETDRS LogMAR (at least one eye with <6/12 vision), was 4% (n=65). Peek correctly identified 50 of 65 children as visually impaired (sensitivity 76·9% [95% CI 64·8–86·5]) and standard E-cards detected 49 of 65 children (sensitivity 75·4% [63·1-85·2]) (table 1). 12 (80%) of 15 children with visual impairment not identified by Peek had a LogMAR score in their worse eye of less than 0·3 and better than or equal to 0·4. With standard E cards, 15 (94%) of 16 children fell within this region of mild visual impairment, suggesting that it was mostly children with milder visual impairment that were missed by Peek and E cards. The specificity of Peek was lower (91%) than that of standard E cards (97%). Peek had a lower positive predictive value (23% [95% CI 17·7–29·4]) than the E card (52% [95% CI 41·1–62·0]) due to Peek’s lower specificity (table 1).

Trial recruitment occurred between March 2, 2015, and March 13, 2015. The final 8-week follow-up period finished on May 8, 2015. Of the 320 public primary schools, 25 were excluded as they already had active school screening programmes. Of the remaining 295 eligible schools, 50 were randomly selected and 25 were allocated to each group (figure 2). The mean distances between the schools in which screening took place and the hospital, and school sizes were similar in each group (table 2). All 27316 potentially eligible children attending the 50 schools were invited for vision screening. Parental consent and child’s assent were granted for 22934 (84·0%) children (78·8% in the standard group and 89·6% in the Peek group), of whom 20863 (91·0%) were assessed during a 2-week period (figure 3).
In this study, 531 (5%) of 10 579 children in the Peek group and 366 (4%) of 10 284 children in the standard group failed the screening test. Of these 897 referred children, 379 (42%) children were boys, with a mean age of 11.6 years (2.9), and 273 (30%) children were in lower primary; characteristics were similar between groups (table 3).

Of the 366 children referred from the standard group, 82 (22%) presented to the hospital during the 8-week follow-up period compared with 285 (54%) of 531 children referred from the Peek group. After adjusting for school clustering, children referred with the Peek school eye health system were more likely to attend hospital within 8 weeks than children referred with the standard screening system (OR 7.35 [95% CI 3.49–15.47]; p<0.0001). When distance from the hospital, age, education level, and sex were also adjusted for, the estimated effect was similar (adjusted OR 8.27 [95% CI 3.77–18.1]; p<0.0001).

The rate of hospital attendance among those who screened positive for visual impairment was significantly higher in the Peek group than the standard group (HR 2.56 [95% CI 1.43–4.56]; p=0.0001; figure 4; table 4). However, because hazards were not proportional (p<0.0001), the time was split into weekly sections and HR was estimated for each week (table 4). This HR estimation was only possible for the first 4 weeks of follow-up because after this time no children arrived to hospital from the standard group. We did not find an intervention effect in week 1 (HR 1.03 [95% CI 0.54–1.98]; p=0.92). However, in week 2, evidence suggests that children referred using Peek had an increased attendance rate, with an estimated HR of 4.63 (95% CI 2.15–9.95; p=0.0001). Stronger intervention effects were seen in weeks 3 (HR 5.01 [95% CI 2.00–12.52]; p=0.0006) and 4 (HR 11.51 [2.41–54.93]; p=0.002).

Of the children referred from schools in the standard group, 37 (47%) of 78 children were confirmed to have visual impairment (four had missing visual acuity data) compared with 68 (25%) of 276 children referred from schools in the Peek group (nine had missing visual acuity data; table 5).
positives were identified among children screened using Peek than among those screened using the standard screening (p<0.0001). However, the absolute number of confirmed visually impaired children was higher in the Peek group (n=68) than the standard group (n=37). Most of the children referred who were not found to have visual impairment in the clinic had a diagnosis of allergic conjunctivitis (139 [67%] of 208 children in the Peek group and 32 [78%] of 41 children in the standard group; table 5). All children who had visually significant refractive error (<6/12) were offered free spectacles and three children had cataract surgery.

Discussion

Early identification and management of visual impairment in children is important to enable participation in education and society. We showed that an integrated system comprising a smartphone-based visual acuity test (Peek Acuity), a printed referral card illustrating the degree of visual impairment, and SMS reminders (ie, the Peek school eye health system) significantly improved the overall hospital attendance rate among children referred compared with the standard system. In this first trial, to assess the use of smartphones for vision screening and referral, we found the test can be effectively delivered by school teachers.

The rate of hospital attendance was initially similar in both groups. However, in the standard group attendance slowed after the first week before stopping completely after 4 weeks. The initial similar attendance in both groups might have been due to early responders who seek medical attention faster. Hospital attendance was better maintained in the Peek group. As the Peek system is an intervention package involving both repeated SMS and a special referral card illustrating visual impairment, which elements led to the increased attendance is unknown. The reminder messages appeared to have no additional effect on attendance after the first two reminders were sent (figure 4).

In the validation study, we found the sensitivity of Peek and the standard E-cards in detecting visual acuity of less than 6/12 to be about 75% when used by school teachers compared with about 100% for ETDRS LogMAR chart used by a clinician. Most of the false negative individuals had an EDTRS LogMAR visual acuity close to the threshold level. The negative predictive values of both tests were very high.

The specificity and positive predictive value were lower for Peek than the standard system, resulting in more children being referred who were not subsequently found to have visual impairment. However, many of them were noted to have an ocular condition. A low positive predictive value could overburden the health system with unnecessary referrals and costs, resulting in increased pressure on limited eye-care services. These false positive results might have arisen for a number of reasons: subtle variation in the smartphone screen angle, reflections off the screen or variation, and increased glare from a bright screen in the presence of inflammatory eye conditions, such as allergic conjunctivitis.

To reduce the false positive rate, we propose additional testing strategies. This involves retesting the vision of all children who initially screened positive. A referral is only triggered if the child fails to meet the threshold acuity on the repeat test. If a child fails the first test and then passes the second test, a third screening test is delivered (maximum three tests per eye). Referral is triggered on confirmation of two of three failed tests. An alternative approach, currently being tested, involves extension of the number of optotypes shown to confirm the acuity level. Additionally, a set number of children who pass the screening test will be prompted by the examiner to deliver a repeat test to enable monitoring of false negative rates.

This trial suggests that, for every 10000 children screened with standard methods, 80 of those are expected to be referred to attend the hospital clinic—38 with visual impairment and 42 without. With the Peek system, 269 children are expected to attend hospital—66 with visual impairment and 203 without. Therefore, with use of the first iteration of the Peek school eye health system an anticipated additional 28 visually impaired children...
Visual acuity is usually delivered as a continuous test variation in visual acuity has been reported previously. Short-term to medium-term test-retest acuity could have fluctuated, accounting for some of the differences. In conclusion, the Peek school eye health system resulted in a substantial increase in the proportion of children who attended the hospital clinic for assessment after screening positive for visual impairment and provided real-time visibility to the health system. This outcome indicates the potential value of this technology in improving uptake of services and encouraging improvement in delivery through identification of areas with potential bottlenecks in the care pathway (such as regions with the highest
number of children who have not attended the hospital). The Peek Acuity screening algorithm used in this trial was less specific than the Tumbling-E card in identifying children with visual impairment. Additionally, ongoing work is required to further refine the testing algorithm, maintaining sensitivity while improving specificity without substantially increasing the testing time and systematically reducing barriers to patient care across the entire patient care pathway.

Contributors
HKR and AB searched the medical literature. HKR, AB, and MJ B conceived and designed the study. HKR, EW, and GLDT collected data. HKR, DM, and HAW did the statistical analysis. HKR, AB, GLDT, DM, HAW, and MJ B interpreted the data. HKR drafted the manuscript, and all authors critically revised the manuscript for important intellectual content. AB and MJ B obtained funding for the study. EW provided administrative, technical, and material support. AB and MJ B supervised the study.

Declaration of interests
The Peek Vision Foundation (09919543) is a registered charity in England and Wales (1165960), with a wholly owned trading subsidiary, Peek Vision Ltd (09937174). MJB is a trustee of the Peek Vision Foundation and AB is Chief Executive Officer of the Peek Vision Foundation and Peek Vision Ltd. All other authors have no competing interests.

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