CLINICAL TRIAL

Randomized Trial of Tablet Computers for Education and Learning in Children and Young People with Low Vision

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SIGNIFICANCE: Mobile devices such as tablet computers have become widely available as mainstream devices and are also used in some schools, but there is an absence of robust information regarding the efficacy of any optical/electronic low vision device or tablet computer in supporting education of young people with low vision.

PURPOSE: A randomized controlled trial (RCT) is needed to measure the impact of tablet computers on education, specifically on independent access to educational material, in children and young people with low vision. We conducted a pilot RCT to determine the feasibility of conducting a full-scale trial.

METHODS: This was a randomized multicenter pilot trial across two sites in the United Kingdom and one site in India. Forty children and young people aged 10 to 18 years with low vision (best-corrected visual acuity for distance between <20/60 [0.48 logMAR] and 20/400 [1.30 logMAR] in the better eye) in the United Kingdom (n = 20) and India (n = 20) were randomized to two parallel arms, with a 1:1 allocation ratio, to control (n = 20) or intervention (n = 20). Control group participants received standard low vision care. The intervention group received a tablet computer (iPad) with low vision applications and instruction in its use, including accessibility features. Four primary outcomes included (1) 6-month recruitment rate, (2) retention of participants for 3 months, (3) acceptance/usage of device, and (4) accessibility of device.

RESULTS: Nineteen participants (95%) enrolled within 6 months in the United Kingdom, and 20 participants (100%), in India. Retention at 3 months was 85% (n = 17) in the United Kingdom and 95% (n = 19) in India. More than one half of participants reported using a tablet computer at school at least once every day. The majority (90%) found it easily accessible.

CONCLUSIONS: This study demonstrated that it is feasible to recruit children and young people with low vision into an international multicenter RCT of electronic assistive technology. Regardless of geographical location, children and young people with low vision reported using tablet computers at least once a day at school and accessed them easily.

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Worldwide, 19 million children younger than 14 years may be visually impaired.¹ Of these, 12 million are visually impaired due to uncorrected refractive errors; 1.4 million children are irreversibly blind.^{1,2} Although there are no accurate estimates of children with low vision, it is likely that around 7 million are affected. Low vision has adverse impacts on education and employment, potentially causing economic hardship in adult life. The World Health Organization has identified and highlighted the provision, education, and use of low vision devices in children as a priority.³ Although optical low vision devices can assist with academic activities, children have reported problems and limitations, such as difficulty with usage, peer pressure, and lack of benefit for attempted tasks (D'Angelo ML et al. IOVS:53:E-Abstract 4426).⁴ Teachers, parents, and young people with sight loss report limited usage of devices, usually for fear of "standing out." Given this, some low vision devices may never be used, and some may not be used to their full potential.⁴

Conventional optical low vision devices are now supplemented by newer assistive technology such as closed-circuit television, computer-screen reading software, audio books, electronic books and newspapers, smartphones, and tablet computers. In addition to facilitating communication, reading, and writing, assistive technology may improve quality of life and facilitate learning.⁵ Factors limiting the use of assistive technology include variable acceptance of these devices, technical problems (particularly time required to set up closed-circuit television in the classroom and to move it between classrooms), battery life, and availability of power supply, as well as other issues including cost and maintenance/repair.^{5–7} Additional drawbacks include lack of portability, poor integration with school information technology networks, and limitations of either input or output functions. In 2002, a study reported that only 50% of students with visual impairment were using assistive technology and only 51% of teachers felt competent to teach their students about assistive technology.⁸

Since then, mobile devices such as tablet computers have become widely available as mainstream devices and are also used in some schools. In adults with low vision, tablet computers increase reading speed and are considered easily accessible.^{9–11} The widespread use of tablet computers may give low vision users a feeling of being included in the general trend. Because of their standard accessibility features, tablet computers, particularly iPads (Apple Inc, Cupertino, CA), can be used for a variety of tasks and have been recommended by low vision organizations such as the Royal National Institute for Blind People, United Kingdom. However, there is an absence of robust information regarding the efficacy of any optical or electronic low vision device or tablet computer in supporting the education of young people with low vision.^{12,13} In the absence of previous randomized controlled trials, we therefore conducted a pilot randomized controlled trial with the primary objective of determining whether a full randomized controlled trial of tablet computers as assistive technology to support education would be feasible. Secondary objectives were to explore acceptability, accessibility, and any changes in vision-related quality of life, functional vision, and measures of reading speed, accuracy, and comprehension.

We gave the study the acronym CREATE (Children Reading with Electronic Assistance to Educate).

METHODS

Trial Design

The Children Reading with Electronic Assistance to Educate study was a multicenter, parallel-group, randomized controlled trial with 1:1 allocation ratio.¹⁴ We enrolled participants at three sites-two in the United Kingdom and one in India. The two participating centers in the United Kingdom were as follows: (a) the Child Development Center in Bedford (a multidisciplinary community health, education, and social care facility for children with developmental needs and disabilities) and (b) the low vision clinic for children and young people at Moorfields Eye Hospital (a tertiary eye care facility) in London. The participating center in India was the Meera and L. B. Deshpande Center for Sight Enhancement, L V Prasad Eye Institute (a tertiary eye care center), Hyderabad. The trial is registered at Clinicaltrials.gov (NCT02798848). The protocol is previously published.¹⁴ The conduct of this trial complied with the ethical standards defined by the Declaration of Helsinki and Good Clinical Practice. The study protocol was approved by National Research Ethics Committee North of Scotland/Grampian (IRAS ID 179658, NRES reference 15/NS/0068) and Ethics Committee for Human Research at the L V Prasad Eye Institute, Hyderabad, India. A parent or guardian gave written informed consent for their child's participation, and all participants gave assent.

Participants

We enrolled children and young people aged 10 to 18 years meeting the World Health Organization definition of low vision: "best-corrected visual acuity for distance between less than 20/60 (0.48 logMAR) and 20/400 (1.30 logMAR) in the better eye." The decision to have two very different settings reflected our desire to provide people in middle-/low-income countries with equal access to innovation and to shorten the timescale of implementation of novel approaches in these settings.

Eligibility Criteria

Children and young people aged 10 to 18 years with low vision were invited to participate. Exclusion criteria were as follows: any disability that could influence the use of low vision devices, current use of a tablet computer for educational purposes (except occasional use for homework), unwilling to participate, no longer in education, and lack of sufficient fluency in English to complete the study.

If participants in the control group started using a tablet computer for education during the study, they were removed from the trial, and no further data were collected.

Interventions

Control Intervention

Participants in the control group received standard low vision care, including optimal refractive correction, tints, optical low vision devices (magnifiers, telescopes), and/or electronic magnifiers, including instructions in their use, and signposting to appropriate services and liaison with teachers for visually impaired and class teachers. None of the participants at sites in the United Kingdom received new low vision devices. However, five participants (50%) in the control group at the Indian site were prescribed new low vision devices (handheld monocular telescope, stand magnifier, mouse closed-circuit television, portable video magnifier). They were provided training in use of the devices by vision therapists in the low vision rehabilitation team at the center. The duration of the training depended on a variety of factors such as the number and complexity of the device, age of the child, and visual acuity of the child. Training averaged approximately 30 minutes of sessions per day for about three to four days per child.

Experimental Intervention

In addition to standard low vision care, the intervention group received an Apple iPad on loan, with instruction in the use of accessibility features and additional low vision applications. For the United Kingdom participants, training in use of the Apple iPad was provided both by the qualified teacher for children and young people with vision impairment and by the optometrists within the low vision clinic. For the Indian participants, training was provided by the optometrists in the low vision clinic and lasted for about two hours (on the day the device was issued) and was supplemented with telephonic assistance in cases where the child had any queries regarding usage, and the issues were resolved. We pre-installed Microsoft Office (Microsoft Corporation, Redmond, WA) installed for word processing and preparation and viewing of slides. Devices in the United Kingdom were WiFi enabled to access school wireless networks, whereas those in India had wireless data (3G) connectivity.

After the initial training session, the local teacher for visually impaired (or their assistant at Bedford) or the researchers (India, London) provided further training as required, either in person or over the phone.

In the United Kingdom and in India, each participant's teacher for the vision impaired was informed of their trial participation. We sent letters to the classroom teacher and the school's special educational needs coordinator, requesting that young people be allowed to use their device in the classroom.

Outcomes

Primary Outcomes

Primary outcome measures related to trial feasibility: (1) recruitment rate over 6 months, (2) retention rate of participants until 3 months after randomization, (3) acceptance and usage of the allocated device, and (4) device accessibility. Given that our target recruitment was 20 participants each at the United Kingdom and India sites over 6 months, our criterion for success was 18 participants (90%) over 6 months or 100% over 7 months. We recorded device usage and acceptance via participant diary, recording the number of hours per day using the device for schoolwork, reading, games, and videos. In one-to-one semistructured interviews at visits 2 and 3, we explored device usage outside education and participants' opinions about the devices.

There was no robust or evaluated method for assessing accessibility of the device used by the intervention group. Investigation of available applications led to the use of a high-contrast touch-based game, Piano Tiles (Cheetah Technology Corporation Limited, Beijing, China). In this game, the player was asked to touch black tiles that moved vertically across the screen while avoiding touching the white tiles. The black tiles are large $(3.6 \times 4.8 \text{ cm})$ and of high contrast at the beginning of the game, but the contrast level reduces with the progression of the game. This game has multiple options, and for this study, we used the Classic mode both for introduction and for the practice session. After the practice session, the participant played the Zen mode over 15 seconds and recorded the best score of three attempts. The score was calculated as the total number of black tiles touched within the 15-second period. The game ended if a white tile was touched in error. The game score was converted to an ordinal variable for capture within the pilot database (consisting of five children with normal and low vision) as follows: score 0 to 15, ordinal variable 0 = low accessibility; 16 to 35, 1 =medium accessibility, and greater than 35, 2 = high accessibility.

Secondary Outcomes

We assessed the effect on functional visual ability using the Cardiff Visual Ability Questionnaire for Children¹⁵ for participants in the United Kingdom and the L V Prasad Functional Vision Questionnaire II¹⁶ for participants in India. Although it would have been desirable to use the same questionnaire in both settings, there was no suitable validated universal questionnaire that could be used across the United Kingdom and India, given the differences in language and activities of daily living across cultures. At all sites, we measured vision-related quality of life with the Impact of Vision Impairment for Children questionnaire.¹⁷ At all the sites, the questionnaires were administered by the same research assistant at each visit, and these were administered at baseline, at visit 2 (3 months after randomization), and at visit 3 (6 months after randomization).

In the United Kingdom, we assessed reading ability and comprehension using the Neale Analysis of Reading Ability (a test of reading accuracy, comprehension, and speed),^{18,19} as well as reading speed and accuracy on the International Reading Speed Texts.²⁰ In both United Kingdom and India, we measured peak reading speed, near visual acuity, and critical print size on the MNREAD test (University of Minnesota, Minneapolis, MN).²¹ While completing the Neale Analysis of Reading Ability and International Reading Speed Texts, participants wore their preferred low vision device, and for the MNREAD, their spectacle correction only. We recorded all reading tests as audio files. Researchers masked to device allocation carried out the analysis. In addition, we recorded any adverse outcomes (loss of motivation, negative peer comments) and accessibility and impact of the allocated device on the participant. We assessed outcomes at baseline (when randomization was performed) and 3 and 6 months after randomization. We estimated the cost of the devices as cost of device and training.

Sample Size

Because this was the first randomized controlled trial of assistive technology for children with low vision, a formal sample size calculation was not possible. We chose a sample size of n = 20, randomized in a 1:1 ratio, in each participating country. A sample size of 20 per group is common in feasibility studies.¹⁴

Randomization

Sequence Generation and Allocation Concealment Mechanism

In the United Kingdom, participants were randomized by a Moorfields senior data manager (WX), using a permuted block design stratified by site. At L V Prasad Eye Institute, we used a Web-based tool (https://www.sealedenvelope.com) for random allocation of the participants, by an optometrist who was not involved in the study.

Implementation

The respective site researchers (MC, HU, RT, VKG, SB, SS) enrolled participants and provided them with the allocated intervention. Masking was not possible.

Statistical Analysis

Participants' demographic and clinical characteristics were summarized as mean and standard deviation, median and interquartile range, and by counts and percentages as appropriate. We generated Rasch-scaled scores for person visual ability (in logits) of the L V Prasad Functional Vision Questionnaire II and Cardiff Visual Ability Questionnaire for Children using previously published raw-to-Rasch conversion spreadsheets.^{15,16} Although the Impact of Vision Impairment for Children was previously validated using Rasch analysis in children with low vision in India, and a revised shorter version was proposed,²² we did not use the spreadsheets to generate Rasch-scaled scores, given that a similar validation analysis was not available for the United Kingdom sample and that the sample size was too small for Rasch analysis. Therefore, to ensure consistency, we decided to use the raw summary scores of the Impact of Vision Impairment for Children for all the sites.

RESULTS

Recruitment

Enrollment took place from March 2016 to December 2016. In London, the first child was enrolled on March 10, at Bedford on May 10, 2016, and in Hyderabad on April 5, 2016. The participant flow is shown in Fig. 1. In the United Kingdom, we assessed a total of 38 children for eligibility. Of these, 18 were excluded: 10 declined to participate, and 8 were already using a tablet computer at school. In India, we assessed a total of 27 children for eligibility. Of these, six were excluded; two declined to participate, and four were no longer in education. One child who underwent vitreoretinal surgery within a week after recruitment in India had to be withdrawn and was replaced with another eligible participant.

Baseline Characteristics

The mean age of the participants in the United Kingdom was 12.6 (standard deviation, 2.4) years in the intervention group and 13.3 (standard deviation, 1.6) years in the control group (Table 1). The mean age of the participants in India was 13.4 (standard deviation, 1.3) years in the intervention group and 14.2 (standard deviation, 2.1) years in the control group. Participant characteristics at randomization are summarized in Table 1

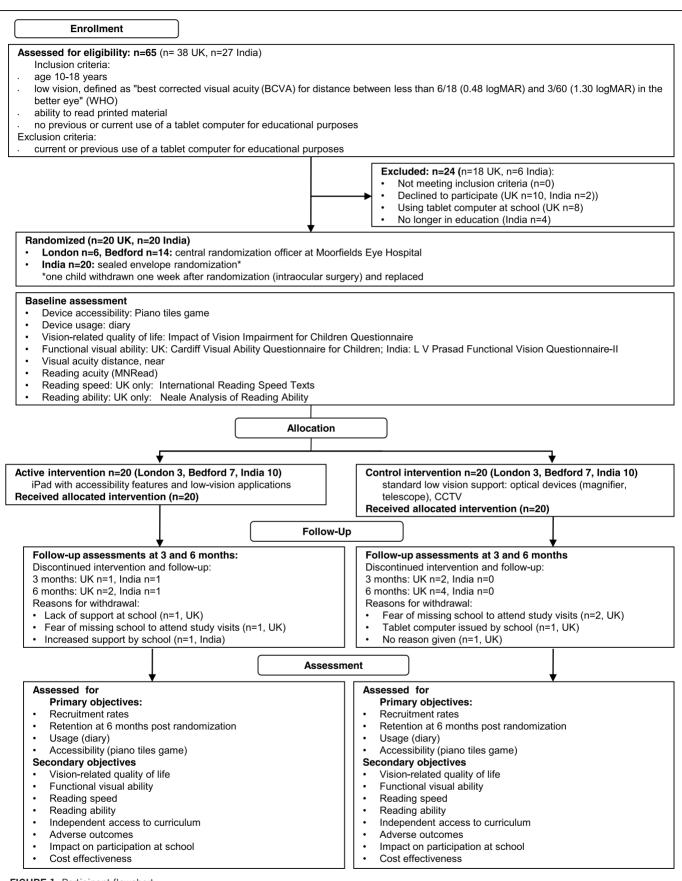


TABLE 1. Participant characterist	ics	
	Control group (n = 10)	Intervention group (n = 10)
United Kingdom (n = 20)		
Age, mean (SD) (y)	13.3 (1.6)	12.6 (2.4)
Male/female, n (%)	6 (60)/4 (40)	5 (50)/5 (50)
Ethnicity, n (%)		
White	6 (60)	6 (60)
Black	0	1 (10)
Asian	3 (30)	3 (30)
Unknown	1 (10)	0
Duration of VI, mean (SD) (y)	7.1 (4.3)	9.3 (3.7)
Baseline distance visual acuity, mean (SD) (logMAR)	0.59 (0.24)	0.71 (0.32)
Baseline near visual acuity, mean (SD) (logMAR)	0.22 (0.27)	0.46 (0.28)
	Control group (n = 10)	Intervention group (n = 10)
India (n = 20)		
Age, mean (SD) (y)	14.2 (2.1)	13.4 (1.3)
Male/female, n (%)	7 (70)/3 (30)	4 (40)/6 (60)
Duration of VI, mean (SD) (y)	11.4 (4.0)	9.3 (5.0)
Baseline distance visual acuity, mean (SD) (logMAR)	0.88 (0.21)	0.86 (0.18)
Baseline near visual acuity, mean (SD) (logMAR)	0.92 (0.17)	0.94 (0.21)
VI = vision impairment.		

and show comparable visual acuity, sex, mean age, and ethnicity in both groups, albeit with a male preponderance in the control group for both the United Kingdom and Indian sites. Participants in control group at the Indian site had worse distance visual acuity as compared with their United Kingdom counterparts (P = .03), but there was no such difference for the intervention group across the sites (P = .22). The near acuity was significantly worse for both the control (P < .0001) and intervention groups (P = .004) at the Indian site as compared with their United Kingdom counterparts (Table 1). Participants completing the trial had a range of ocular pathologies, although retinal dystrophies and degenerations were the most common cause of vision impairment across all the centers (Table 2).

Numbers Analyzed

In the United Kingdom, data from 17 participants were included in the analysis of data 3 months after randomization and 14 participants at 6 months. In India, data from 19 participants were available for analysis at the 3- and 6-month time points.

Primary Outcomes

Recruitment Rates

In the United Kingdom, the target number of 20 participants was reached within 7 months, and 19 (95%) of 20 were enrolled within 6 months (in London, the last participant was enrolled on September 9, and in Bedford, on December 12, 2016). In

India, the target enrollment of 20 participants was reached within 6 months.

Retention Rates

In the United Kingdom, the retention rate was 85% (n = 17) at 3 months and 70% (n = 14) at 6 months. Of the six participants who did not complete visit 3 (6 months), two belonged to the intervention and four to the control group. In the intervention group, one participant lacked support for usage of the device at school, and the other had concerns about missing school to attend study visits. In the control group, one participant had a tablet computer issued by the school during the study period, two had concerns about missing school to attend study visits, and one withdrew without giving any reason.

In India, the retention rate was 95% (n = 19) at visits 2 (3 months) and 3 (6 months). The child who withdrew belonged to the intervention group and received sufficient support from teachers at school, so the iPad was returned within 1 month after randomization.

Acceptance and Usage of Allocated Device

The quality of the diary entries for data collection was poor. Among the United Kingdom participants, none in the control group completed their diaries. By comparison, two participants in the intervention group provided complete diary data, and the remaining participants provided only partially complete diary data at visits 2 and 3. In India, four participants in the control group provided less than 50% of complete diary data at visit 2, but seven participants provided at least 50% complete diary data at visit 3. Furthermore, six participants in the intervention group provided at least 75% complete diary data at visit 2 as compared with nine participants at visit 3.

In the United Kingdom, six participants (67%) reported using the iPad at school at least once every day at the 3-month visit

TABLE 2. Causes of vision impairment

	United	
Cause of sight impairment, n (%)	Kingdom	India
Retinal dystrophy/degenerations*	6 (30)	10 (50)
Albinism (ocular/oculocutaneous)	5 (25)	3 (15)
Optic atrophy with cerebral visual impairment	2 (10)	1 (5)
Retinopathy of prematurity	1 (5)	1 (5)
Wolfram syndrome†	1 (5)	0
Congenital stationary night blindness	1 (5)	0
X-linked retinoschisis	1 (5)	0
Macula scar	1 (5)	0
Radiotherapy-related cataract	1 (5)	0
Aniridia	1 (5)	0
Uveal coloboma	0	3 (15)
Retinoblastoma	0	1 (5)
High myopia with ametropic amblyopia	0	1 (5)
Total	20 (100)	20 (100)

*Includes retinitis pigmentosa, rod monochromatism, Stargardt disease, Leber congenital amaurosis, cone dystrophy, and rod-cone dystrophy. †Diabetes insipidus, diabetes mellitus, optic atrophy, and deafness. TABLE 3. Frequency of use of tablet computers at school and at home

	United Kingdom				India			
	Tablet computer usage at school		Tablet computer usage at home		Tablet computer usage at school		Tablet computer usage at home	
	3 mo from baseline	6 mo from baseline	3 mo from baseline	6 mo from baseline	3 mo from baseline	6 mo from baseline	3 mo from baseline	6 mo from baseline
	n = 9 n = 8		n = 9 n = 8		n = 9 n = 9		n = 9	n = 9
Every day at least once (n)	6	4	3	6	6	8	8	7
Once a week or less (n)	2	2	6	2	1	1	1	1
Never (n)	1	2	0	0	2	0	0	1
Withdrawn from study (n)	1	2	1	2	1	1	1	1

(Table 3). By comparison, only three participants (33%) reported using the iPad at home at least once on a daily basis at 3 months. One participant never used the tablet computer and withdrew from the study at visit 2 (3 months from baseline). At 6 months, median (interquartile range) tablet computer usage in the United Kingdom was 0.75 (0.5 to 3.25) hours for reading, 0.5 (0 to 1) hours for playing games, and 0.5 (0 to 1) hours for watching videos (Table 4).

In India, six participants (67%) reported using the iPad at school at least once every day at the 3-month visit (Table 3). By comparison, eight participants (89%) reported using the iPad at home at least once on a daily basis. Two children never used it at school, and one of them withdrew from the study at visit 2. Overall, there was greater usage of the iPad for reading than for other tasks such as playing games and watching videos (Table 4).

When compared with use of the allocated device in the intervention group, participants in the control group reported less use of their low vision devices for tasks such as reading or board work at visits 2 and 3.

Accessibility of Tablet Computers

Using the Piano Tiles game, high accessibility was recorded in 9 (90%) of 10 participants, and low accessibility in 1 (10%) in the United Kingdom. The participant with low accessibility withdrew

from the study by visit 2. At the Indian site, except for the one participant (10%) who withdrew from the study, accessibility was high (90%).

Secondary Outcomes

Functional Visual Ability and Vision-related Quality of Life

In the United Kingdom, the mean functional visual ability as measured using the Cardiff Visual Ability Questionnaire for Children was -0.32 (standard deviation, 0.79) logits for the whole group at baseline, and this did not appear to change during the observation period in either treatment arm. Median vision-related quality of life as measured using the Impact of Vision Impairment for Children questionnaire at baseline was 73 (interquartile range, 65 to 76) for the whole group, indicating markedly reduced vision-related quality of life. This too did not appear to change during the observation period in either study arm (Table 5).

In India, the mean functional visual ability as measured using the L V Prasad Functional Vision Questionnaire II was –0.67 (standard deviation, 0.45) logits for the whole group at baseline, and this did not appear to change during the observation period in either treatment arm. Median vision-related quality of life as measured using the Impact of Vision Impairment for Children questionnaire at baseline was 93 (interquartile range, 79 to 97.5) for the whole

	United Kingdom*			India						
	Tablet computers		Tablet c	omputers	Conventional low vision devices					
	3 mo from baseline	6 mo from baseline	3 mo from baseline	6 mo from baseline		3 mo from baseline	6 mo from baseline			
Activity	n = 9	n = 8	n = 9	n = 9	Activity	n = 10	n = 10			
Reading, median (IQR) (h/d)	0.50 (0.19–1)	0.75 (0.50–3.25)	0.84 (0.54–1.89)	1.54 (0.51–2.31)	Reading	0.21 (0.05–0.42)	0.54 (0.12–0.75			
Playing games, median (IQR) (h/d)	0.13 (0–0.70)	0.5 (0–1)	0.52 (0.44–1.10)	0.37 (0.29–0.37)	Board work†	0.21 (0.06–0.41)	0.24 (0.05–1.33			
Watching videos, median (IQR) (h/d)	0.5 (0–1)	0.5 (0–1)	0.30 (0–0.52)	0.18 (0.13–0.25)	—	_	—			
Other, median (IQR) (h/d)	0	0.25 (0–1)	0.44 (0.12–1.14)	0.04 (0–0.67)	Other	Not used	0.01 (0-0.09)			

*For participants in the United Kingdom, data regarding usage were collected for tablet computer only. †Data available for seven participants only; three participants used the device but did not record the time in dairy. IQR = interquartile range.

	Base	eline	3	mo	6 mo		
	Tablet computer	Conventional LVD	Tablet computer	Conventional LVD	Tablet computer	Conventional LVD	
	n = 10	n = 10	n = 9	n = 8	n = 8	n = 6	
Functional visual ability (CVAQC), mean (SD) (logits)	-0.20 (0.94)	-0.43 (0.60)	-0.47 (0.87)	-0.26 (0.70)	-0.38 (1.01)	-0.35 (0.34)	
	n = 9	n = 10	n = 8	n = 8	n = 7	n = 6	
Vision-related quality of life (IVI-C) score, median (IQR)	68 (61–77)	75 (65–77)	69 (66–93)	71 (63–82)	71 (71–78)	64 (56–85)	
	n = 10	n = 10	n = 9	n = 8	n = 8	n = 6	
Reading speed (IReST), median (IQR), wpm	73.5 (39–126)	109 (64–138)	72 (43–128)	76 (56–137)	67 (40–90)	98 (42–148)	
	n = 10	n = 10	n = 9	n = 8	n = 8	n = 6	
Critical print size,* median (IQR) (logMAR)	1.02 (0.47–1.02)	0.7 (0.42–1.02)	0.8 (0.5–0.5)	0.7 (0.45–0.8)	0.97 (0.52–0.52)	0.65 (0.45–0.92)	
	n = 10	n = 10	n = 9	n = 8	n = 8	n = 6	
NARA errors, median (n)	2 (2–3)	3 (1–5)	0 (0–3)	1 (0–1)	1 (0–2)	1 (0–3)	
NARA, comprehension score, median (IQR)	0.75 (0.47–0.78)	0.5 (0.34–0.88)	0.75 (0.5–0.88)	0.69 (0.39–0.75)	0.81 (0.66–0.88)	0.69 (0.5–0.88)	

TABLE 5. Secondary outcome measures for participants in the United Kingdom

*Assessed using MNREAD chart. CVAQC = Cardiff Visual Ability Questionnaire for Children; IQR = interquartile range; IReST = International Reading Speed Texts; IVI-C = Impact of Vision Impairment for Children questionnaire; Logits = log (odds ratio); LVD = low vision device; NARA = Neale Analysis of Reading Ability; wpm = words per minute.

group, indicating markedly reduced vision-related quality of life. This too did not appear to change during the observation period in either study arm (Table 6).

Reading Speed, Critical Print Size, and Comprehension

Reading data are presented in Table 5. The overall median reading speed at baseline using the International Reading Speed Texts across all participants in the United Kingdom was 81 words per minute (interquartile range, 50 to 134 words per minute); it did not appear to significantly change at visits 2 and 3. The overall critical print size at baseline using the MNREAD chart across all participants in the United Kingdom was 0.75 logMAR (interquartile range, 0.47 to 1.02 logMAR); it also did not appear to significantly change at visits 2 and 3. The overall critical print size at baseline using the MNREAD chart across all participants in India was 1.3 logMAR (interquartile range, 1.18 to 1.44 logMAR); it did not appear to change significantly change at visits 2 and 3.

Reading Accuracy and Comprehension

The overall median reading accuracy at baseline using Neale Analysis of Reading Ability across all participants in the United Kingdom was 2 errors (interquartile range, 1 to 4 errors), and the median comprehension score was 0.69 (interquartile range, 0.38 to 0.84). Neither accuracy nor comprehension changed between the visits.

Qualitative Outcomes

In the United Kingdom, participants used the tablet computer to gain access to the curriculum by installing textbooks and by

	Base	line	3	mo	6 mo		
	iPad	Conventional LVD	iPad	Conventional LVD	iPad	Conventional LVD	
	n = 10	n = 10	n = 9†	n = 10	n = 9†	n = 10	
Functional visual ability (LVP-FVQ II), mean (SD) (logits)	-0.44* (0.40)	–0.76 (0.38)	-0.62 (0.39)	-0.89 (0.36)	-0.11 (0.40)	-0.78 (0.27)	
	n = 10	n = 10	n = 9†	n = 10	n = 9†	n = 10	
Vision-related quality of life (IVI-C) score, median (IQR)	84.5 (75.7–95.2)	93.5 (93–97.7)	88 (73–98)	99.5 (90–102.2)	91 (81–94)	100.5 (97–104.5)	
	n = 10	n = 10	n = 9	n = 10	n = 9	n = 10	
Critical print size,‡ median (IQR) (logMAR)	1.18 (1.18–1.44)	1.31 (1.20–1.49)	1.1 (1.1–1.42)	1.32 (1.1–1.42)	1.15 (1.15–1.42)	1.2 (1.2–1.42)	

*Higher negative scores on LVP-FVQ II indicate greater functional visual ability. †One participant returned the iPad 1 month after recruitment. ‡Assessed using MNREAD chart. IQR = interquartile range; IVI-C = Impact of Vision Impairment for Children questionnaire; Logits = log (odds ratio); LVD = low vision device; LVP-FVQ II = L V Prasad Functional Vision Questionnaire II.

taking photographs for on-screen enlargement of paper-based worksheets. Many participants also installed scientific calculators and digital periodic tables. Participants liked that the tablet computers were quick and easy to operate in a classroom environment when compared with closed-circuit television and laptops with student camera. In India, participants used the iPad to gain access to board work by using the zoom feature to magnify the content on the board so that they could follow the lessons at the same time as that of their peers. In addition, they found the iPad convenient, as a single device could be used for multiple tasks such as reading, accessing the internet, and watching videos. Both in the United Kingdom and in India, the vast majority of participants enjoyed using the device at school, and there were no negative peer comments. Table 7 provides examples of statements extracted from semistructured interviews with the participants, feedback letters from the teacher, and feedback from parents regarding their opinion about the allocated device in the intervention group.

The main negative feedback from participants and parents in the intervention group arose when students were not allowed access to the school intranet owing to security issues. In addition, some participants felt that the device was underutilized, and they were not able to use all of the accessible features.

DISCUSSION

This pilot randomized controlled trial was performed to evaluate potential difficulties in conducting a full-scale randomized controlled trial to evaluate efficacy of using tablet computers as assistive technology to support education in children and young people with low vision. Experience from this feasibility study, using the study design and treatment regimens for the intended full randomized controlled trial, was to be used to identify any issues related to recruitment, retention, and adherence with study visits. Our results demonstrated that it was feasible to carry out an international multicenter randomized controlled trial of tablet computers as assistive technology to support education in children and young people with low vision. Furthermore, once recruited into this multicenter trial, only few participants dropped, and most completed the entire 6-month duration of the study. We observed high accessibility, acceptance, and usage of the intervention device (tablet computer), with it being used frequently at school by more than one half of the participants.

In this pilot randomized controlled trial, we had four primary outcome measures, and all of these were related to trial feasibility (recruitment, retention, acceptance, accessibility). We included measures of visual function and reading as secondary outcome measures; however, we did not find any significant difference in the effect between the two groups. Given that reading largely depends on the font size and visual field presented, this perhaps is not a surprising finding. We acknowledge that our definitive trial will need to address the question of whether tablet computers will enable greater independence in accessing information as well as educational content and possibly whether this would translate into greater educational achievement.

We assessed vision-related quality of life using the Impact of Vision Impairment for Children at 3 and 6 months in this trial and agree that in a full trial, using educational outcomes, changes in

TABLE 7. Examples of statements extracted from the feedback letters and semistructured interviews		
Statement	Source	Location
"I liked using the tablet computer because it was easier than a laptop; it is small and the other children thought it was cool."	Child	United Kingdom
"I prefer the tablet computer (to my laptop or mobile phone) as it has a nice-sized, clear screen; it is nice and light to hold close to read. My friends and family think the iPad is good too."	Child	United Kingdom
"I prefer to use the iPad because it serves multiple purposes in that I can use it for reading, watching videos, and accessing the Internet."	Child	India
"I have stopped using my laptop and now use the tablet computer instead as it is faster and easier to carry around."	Child	United Kingdom
"I prefer using the iPad as it makes boardwork a lot easier compared with the telescope."	Child	India
"The tablet computer was a great tool to aid the visually impaired pupil in accessing the curriculum, such as the ability to zoom in on reading books and to use a large calculator."	Teacher	United Kingdom
"The student uses the iPad very well, and it has helped him to learn on his own at home. It is difficult for him to see the board, understand concepts, and copy the notes. The iPad enabled him to zoom the text and understand the concepts easily while I am teaching in the class."	Teacher	India
"The pupil uses the camera function on the tablet computer to be able to magnify and look at resources in class. She likes how easy it is to transport around as it less heavy and bulky than the (student camera) laptop and also that it switches on instantly and has a long battery life. She makes use of the scientific calculator app on it and also has a periodic table. She does use the keyboard to type but prefers to handwrite."	Teacher	United Kingdom
"The student finds it very useful in math, physics, and chemistry classes and is performing very well with the iPad."	Teacher	India
"All work is put on the tablet computer. Their behavior has improved; they have moved up sets and have won awards at school is now reading for pleasure on the tablet computer."	Parent	United Kingdom
"My child was able to use the camera to read the menu when out for a meal and uses (the tablet computer) to read things and help find information."	Parent	United Kingdom
"My child used his tablet computer for everything. This has helped him so much at school and at home. It has made him more independent. He uses his camera if he can't see something. It helps him to be able to cook and watch TV; he uses it at the bus stop and train stations and for finding out information."	Parent	United Kingdom

vision-related quality of life would better be measured at 6 months or even later time points. Diaries are frequently disappointing as was our experience in the pilot trial. Therefore, we plan to use monitoring applications installed on the iPads, such as Moment— Screen Time Tracker, which monitors total duration of usage and which applications/software have been used as an appropriate measure of adherence and usage for education.

As part of our exploratory study, we included functional visual ability measures (Cardiff Visual Ability Questionnaire for Children; L V Prasad Functional Vision Questionnaire II) and reading ability measures (Neale Analysis of Reading Ability, International Reading Speed Texts, and MNREAD) as secondary outcome measures in the pilot trial. However, it is difficult to attribute improvement in these measures solely to the use of tablet computer as a device, because reading fluency itself is likely to improve over the 6-month period with passage of time. We believe that cognitive development over 6 months leading to an improvement in reading ability would be similar across both the intervention and control groups. In future trial, we plan to use educational (and not vision-related) outcomes as our primary outcome measures, and similar to the pilot trial, participants in the control group would receive optical devices.

Given that we did not move participants from one group to another, there was no crossover in the conventional sense. However, participants moved themselves, either by obtaining a tablet computer outside the trial or by not using the allocated device. This may preclude the actual feasibility of a full trial in a high-income setting such as in the United Kingdom. If a trial protocol is developed, analysis would be completed on an intent-to-treat basis.

Limitations of our study include a potential selection bias during eligibility assessment, as we approached families known to our low vision services, rather than consecutively presenting new patients. At the Indian site, potential participants from outside the city of Hyderabad were not included, as we anticipated poor attendance at follow-up visits. We found completion of a daily diary to be unreliable to monitor device usage. At all the sites, diaries were frequently incomplete. By comparison, semistructured interviews at follow-up appointments provided more detailed data regarding use and acceptance. It should be noted that, although we collected data on device usage for the present feasibility study, we do not propose to use it as an outcome measure for a future trial. Instead, we envisage that a future trial would address the question of whether independent learning is enhanced by using electronic devices rather than conventional devices or enlarged print material. Nonetheless, as noted previously, if device usage were to be measured in a future trial, we would consider using a monitoring application on the device, such as Moment-Screen Time Tracker. This application monitors total duration of usage and the type of applications/software that have been used by the participant. There are privacy concerns associated with this method, which would need to be discussed at the ethics committee level before implementation.

Although we made some attempts to mask our assessors measures (such as reading assessments), it was not possible to mask the observers during the administration of questionnaires (Impact of Vision Impairment for Children, Cardiff Visual Ability Questionnaire for Children, L V Prasad Functional Vision Questionnaire II). Additional research team members would have improved data masking. Finally, given the nature of the intervention, it was not possible to mask participants to the intervention. This may have introduced some bias in participant's self-reports regarding preference of the device and its usability. In future trials, it will be useful to explore other potential outcome measures such as improvement in school grades or perceived social stigma related to use of optical devices, to demonstrate changes with tablet computer.

We used three diverse international sites to represent a wide spectrum of children and young people with visual impairment and therefore expect that our findings will apply to a wide range of settings.

Barriers to Recruitment

In the United Kingdom, the major barrier to recruitment was that potential participants were already using tablet computers. Although this is encouraging, it does imply that a control arm may be difficult to recruit in future trials. We did not encounter this problem at the Indian site. Instead, there were other barriers such as poor willingness to attend study visits, perhaps owing to a lack of knowledge of the efficacy of low vision rehabilitation; uncertainty about schools permitting the use of the iPad; and parental discomfort with taking responsibility for the device. Further work emphasizing the benefits of these devices may increase recruitment in future studies.

Barriers to Retention

Time away from school for study visits was a factor cited for withdrawal of participants from both active intervention and control groups in the United Kingdom, but not in India. Scheduling visits away from term time may help with this, although care should be taken to avoid withdrawing devices near examination times.

Acceptance and Usage

Qualitative outcomes showed that participants used the devices to access the curriculum independently and to supplement their learning experience.

Adverse Events

No negative peer remarks were reported. In India, participants reported that other students thought the devices were "cool" when compared with optical magnifiers, which can be poorly accepted owing to the fear of "standing out."^{23,24} Some students in India were frustrated by difficulties accessing school wireless fidelity and intranet networks. Additional communication with school information and technology services, and more support for class teachers, may also help improve usage of the device.

Although our study was not powered to measure changes in reading speed, reading accuracy, or vision-related quality-of-life measures, there did not appear to be any change in these parameters over the course of the study. It may be that a longer duration of follow-up or a larger sample size would reveal changes in these parameters.

Finally, it was difficult to ask participants to return a device that they found helpful at the end of the trial. To minimize the ethical issues of removing a potentially useful educational tool from study participants, potential future trials should ensure that all participants are issued with a device at the end of the trial.

In conclusion, it is feasible to recruit children and young people with low vision into an international randomized controlled trial to test the effect of electronic assistive technology. Although our study was not powered to measure changes in reading speed, reading accuracy, or vision-related quality of life measures, there did not appear to be any change in these parameters over the course of the study. Longer follow-up or a larger sample size may reveal changes in these parameters.

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REFERENCES

1. Pascolini D, Mariotti SP. Global Estimates of Visual Impairment: 2010. Br J Ophthalmol 2012;96:614–8.

 Kong L, Fry M, Al-Samarraie M, et al. An Update on Progress and the Changing Epidemiology of Causes of Childhood Blindness Worldwide. J AAPOS 2012;16:501–7. **3.** World Health Organization. The Management of Low Vision in Children: Report of a Who Consultation, July 1992. Bangkok: World Health Organization, Geneva; 1992. WHO/PBL/93.27.

4. Gnyawali S, Shrestha JB, Bhattarai D, et al. Optical Needs of Students with Low Vision in Integrated Schools of Nepal. Optom Vis Sci 2012;89:1752–6.

5. Alves CC, Monteiro GB, Rabello S, et al. Assistive Technology Applied to Education of Students with Visual Impairment. Rev Panam Salud Publica 2009;26: 148–52.

6. Soderstrom S, Ytterhus B. The Use and Non-use of Assistive Technologies from the World of Information and Communication Technology by Visually Impaired Young People: A Walk on the Tightrope of Peer Inclusion. Disabil Soc 2010;25:303–15.

7. Kapperman G, Sticken J, Heinze T. Survey of the Use of Assistive Technology by Illinois Students Who Are Visually Impaired. J Vis Impair Blind 2002;96:106–8.

8. Abner G, Lahm E. Implementation of Assistive Technology with Students Who Are Visually Impaired: Teachers' Readiness. J Vis Impair Blind 2002;96:98–105.

9. Crossland MD, Silva RS, Macedo AF. Smartphone, Tablet Computer and E-reader Use by People with Vision Impairment. Ophthalmic Physiol Opt 2014;34:552–7.

10. Mednick Z, Jaidka A, Nesdole R, et al. Assessing the iPad as a Tool for Low-vision Rehabilitation. Can J Ophthalmol 2017;52:13–9.

11. Gill K, Mao A, Powell AM, et al. Digital Reader vs Print Media: The Role of Digital Technology in Reading Accuracy in Age-related Macular Degeneration. Eye (Lond) 2013;27:639-43.

12. Barker L, Thomas R, Rubin G, et al. Optical Reading Aids for Children and Young People with Low Vision. Cochrane Database Syst Rev 2015;CD010987.

13. Thomas R, Barker L, Rubin G, et al. Assistive Technology for Children and Young People with Low Vision. Cochrane Database Syst Rev 2015;CD011350.

14. Crossland MD, Thomas R, Unwin H, et al. Tablet Computers Versus Optical Aids to Support Education and Learning in Children and Young People with Low Vision: Protocol for a Pilot Randomised Controlled Trial, Create (Children Reading with Electronic Assistance to Educate). BMJ Open 2017;7:e015939.

15. Khadka J, Ryan B, Margrain TH, et al. Development of the 25-item Cardiff Visual Ability Questionnaire for Children (CVAQC). Br J Ophthalmol 2010; 94:730–5.

16. Gothwal VK, Sumalini R, Bharani S, et al. The Second Version of the L V Prasad-functional Vision Questionnaire. Optom Vis Sci 2012;89:1601–10.

17. Cochrane GM, Marella M, Keeffe JE, et al. The Impact of Vision Impairment for Children (IVI_C): Validation of a Vision-specific Pediatric Quality-of-life Questionnaire Using Rasch Analysis. Invest Ophthalmol Vis Sci 2011;52:1632–40.

18. Douglas G, Grimley M, Hill E, et al. The Use of the NARA for Assessing the Reading Ability of Children with Low Vision. Br J Vis Impair 2002;20:68–75.

19. Hill E, Long R, Douglas G, et al. Neale Analysis of Reading Ability for Readers with Low Vision. A Supplementary Manual to Aid the Assessment of Partially Sighted Pupils'reading Using the Neale Analysis of Reading Ability (NARA). Birmingham, UK: Visual Impairment Center for Teaching and Research: School of Education; University of Birmingham; 2005.

20. Trauzettel-Klosinski S, Dietz K, IReST Study Group. Standardized Assessment of Reading Performance: The New International Reading Speed Texts IReST. Invest Ophthalmol Vis Sci 2012;53:5452–61.

21. Legge GE, Ross JA, Luebker A, et al. Psychophysics of Reading. VIII. The Minnesota Low-vision Reading Test. Optom Vis Sci 1989;66:843–53.

22. Gothwal VK, Sumalini R, Irfan SM, et al. Rasch Analysis of Impact of Vision Impairment for Children Questionnaire. Optom Vis Sci 2013;90:820–7.

23. Mason H. Blurred Vision: A Study of the Use of Low Vision Aids by the Visually Impaired Secondary School Pupils. Br J Vis Impair 1999;17:94–7.

24. Tadić V, Hundt GL, Keeley S, et al. Seeing It My Way: Living with Childhood Onset Visual Disability. Child Care Health Dev 2015;41:239–48.