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Pilot randomized controlled trial protocol: Tablet computers versus optical aids to support education and learning in children and young people with low vision

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Title: Pilot randomized controlled trial protocol: Tablet computers versus optical aids to support education and learning in children and young people with low vision

Acronym: CREATE – Children Reading with Electronic Assistance To Educate

Based on protocol version 2, November 1, 2015

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The sponsor has not influenced the design, running or any other part of this work.

Keywords

Vision, Low vision, Assistive technology, Adolescent, Child

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Abstract

Background: Low vision and blindness adversely affect education and independence of children and young people. New "assistive" technologies such as tablet computers can display text in enlarged font, read text out to the user, allow speech input and conversion into typed text, offer document and spreadsheet processing, and give access to wide sources of information such as the internet. Paediatric low vision research has to date been limited to case series.

Methods: We will carry out a pilot randomized controlled trial (RCT) to assess the feasibility of a full RCT of assistive technologies for children/young people with low vision. We will recruit 40 students age 10-18 years in India and the UK, whom we will randomise 1:1 into two parallel groups. The active intervention will be Apple iPads; the control arm will be the local standard low-vision aid care. Primary outcomes will be acceptance/usage, accessibility of the device and trial feasibility measures (time to recruit children, loss to follow up). Exploratory outcomes will be validated measures of vision-related quality of life for children/young people as well as validated measures of reading and educational outcomes. In addition, we will carry out semi-structured interviews with the participants and their teachers.

Discussion: Participants have been enrolled between March 10 and December 6 2016, and are in follow-up until June 2017. This pilot RCT will assist the design of a full RCT which is needed to advise young people, parents and teachers on the potential usefulness of new assistive technologies.

Trial registration: Clinicaltrials.gov NCT02798848, IRAS ID 179658, NRES reference 15/NS/0068, UCL reference 15/0570. **Funding:** British Council for the Prevention of Blindness

Strengths - Enrolment in different settings, pragmatically exploring feasibility

- low selection, performance and detection bias

Limitations: - small sample size

- performance and social desirability bias (masking of participants not possible)

- possible differential bias between study arms (attractiveness of active intervention)

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Background

People are considered to have "low vision" when their corrected visual acuity (VA) is less than 6/18 in their better eye, or their visual field is less than 10 degrees from the point of fixation, but they use, or are potentially able to use, vision for the planning and/or execution of a task (1). There is an overlap with the definitions of visual impairment and severe visual impairment/blindness. Low vision affects almost 3 million children worldwide (2, 3). It adversely affects educational and employment opportunities, causing economic hardship in adult life (4) (5). Early assessment, provision of low vision aids (LVAs) and training in their use are essential to improve functional vision and to allow children to fully participate in education and improve their quality of life (QoL). In recent years, LVAs have been complemented by "assistive technologies" (AT). These include electronic vision enhancement devices such as closed circuit video magnifiers (CCTV), computer screen reading software, digital audio books, periodicals and computerized text which can be accessed via computers, mobile phones, MP3 players or as printouts in large print or Braille. Assistive technology may enhance reading and writing skills, as well as communication with the world on an equal basis, thereby improving the quality of life of people with low vision and facilitating the learning process (6). However, ATs have certain own limitations. Some of these include lack of portability, poor integration with school information technology networks, and limitations of either input or output functions. Furthermore, teachers, parents, and young people with low vision also report limited use of prescribed LVAs , usually for fear of "standing out".

Tablet computers may help overcome many of these problems, as they are portable, capable of running a wide range of software and of accessing wireless networks. More importantly, acceptability by young people may be high. Numerous applications are available, such as screen magnifiers, optical character recognition and text-to-speech conversion. All manufacturers provide "accessibility features". The Apple iPad, recommended by low-vision support charities such as the Royal National Institute for Blind People and the Royal London Society for the Blind, increases reading speed in adults with low vision (7) and is used by many

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people with low vision (8).

Tablet computers are of considerably lower cost (around £400-1,600 per student) than current standard classroom technology, i.e. CCTV (around £6,400 with distance and near camera, per student). They offer the additional advantages of direct access to school intranets, social acceptability, and word document and spreadsheet processing. Additionally, the price of tablet computers is likely to fall, whereas CCTVs have remained at similar prices for more than 20 years. In the UK, support funding for children and young people with visual impairment (VI) in Local Authority maintained settings has traditionally been administered by their local authority. There is increasingly a shift of funding streams, for example, children with VI may attend educational settings which are not funded or maintained by the Local Authority; or individual funding may be agreed with the family ("self-directed support"). Robust information about the performance of different devices is vitally important not only for educational settings, but also for families and carers.

We have carried out two systematic Cochrane reviews of the paediatric low-vision literature, and have found that to date, no clinical trials of AT for young people with low vision have been conducted (9, 10). Instead, the literature is limited to small non-randomised case series and cohort studies, mostly of optical devices. Informal discussions with young people with VI, their families and teachers indicate that those who have access to tablet computers such as Apple iPads find their accessibility features very useful, and would support research comparing this AT with conventional LVAs.

Objectives

Our hypothesis is that tablet computer-based AT may have high acceptability and usage by children and young people with low vision, and may improve their functional vision (FV), vision-related quality of life (VRQoL) and access to education. As no preliminary data on trial feasibility are available, we will carry out a pilot study to assess whether or not a definitive trial exploring this issue is feasible.

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Primary objective

The principal research question is: "Is it feasible to recruit young people with low vision into a randomised controlled trial testing the effect of an electronic assistive technologies on reading, educational and quality of life outcome measures?"

Secondary research questions/objectives are:

1) Is the active intervention (tablet computer) acceptable to young people, their families/carers, and their teachers?

2) Is the active intervention accessible, and do participants use it?

3) Estimate vision-related quality of life measures, functional vision measures, and reading and educational outcome measures by intervention group at 6 months

4) Have there been any adverse events (loss of motivation, negative peer comments) about using the assistive technology?

5) What are the costs associated with the active intervention?

Trial design

This a parallel 1:1 two arm pilot RCT; the experimental intervention will be an Apple iPad tablet computer with low-vision-applications, and the control intervention will consist of the conventional low-vision support as per standard clinical care, which includes optical LVA and/or CCTV.

Methods

Study setting

There will be three recruitment sites, one in India (L V Prasad Eye Institute [LVPEI], Hyderabad, Telangana -

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Meera and L B Deshpande Centre for Sight Enhancement, a tertiary eye care hospital) and two in the UK (Child Development Centre in Bedford, and the Low Vision Aid Clinic for children and young people at Moorfields Eye Hospital, a tertiary eye care facility in London). The decision to have two very different settings reflects the study funders' aim to provide people in low-income countries with equal access to innovation, and to shorten the timescale of implementation of novel approaches in low-income settings.

Eligibility criteria

Inclusion criteria: We will include young people age 10-18 years with low vision, defined as "best corrected visual acuity (BCVA) for distance between less than 6/18 (0.48 logMAR) and 3/60 (1.30 logMAR) in the better eye" (WHO), who are able to read printed material and who are not currently using, and have not previously used, tablet computer for educational purposes (Fig. 1). We will include students who have access to a tablet computer already, but do not use it for educational purposes. We will include students who use a laptop. We will also include students who use or have previously used optical low-vision aids such as magnifiers, telescopes and CCTV systems.

Exclusion criteria: Young people who are currently using or are prior users of a tablet computer for educational purposes will be excluded.

Near visual acuity equivalent to 6/18 (0.48 logMAR) or better will not be an exclusion criterion, as even though students may perform well on a near acuity test, their reading acuity may be less than the near acuity measured in a clinical setting. Furthermore, as functional reading acuity can gradually reduce over the course of the day, there may be an increase in the need for optical magnification towards the end of the day, and when completing homework. Figure 1 summarises the design of the trial; each of the trial aspects is described in detail below.

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Interventions

The **active Intervention** will be the use of a tablet computer at school and at home. The device will run word processing, spreadsheet and slide presentation files (Microsoft Office for iPad). These will allow students to import documents from the school's learning environment onto their device, work on them, and export them back to the teacher. Users will be given information and instruction on Voiceover (text-to-speech), magnification and contrast settings in the iOS software. In addition, we will install the video magnifier, colour identifying and image recognition application "ViaOpta Daily", which can simultaneously scan and enlarge text.

None of these applications is a medical device; they therefore do not require CE marking (confirmed by MHRA). We will activate the device accessibility features and install the applications before participants receive the devices. Study optometrists will train participants in the use of devices, features and applications. In Bedford, a teacher for the vision-impaired will support this training. We envisage an initial training session of two hours in the first week, followed by telephone support or additional training sessions if required.

The **control intervention** will consist of the standard low-vision care, i.e. optimal refractive correction, tints, optical devices (magnifiers, telescopes),CCTV, training in use of the devices, signposting to appropriate services, and liaison with teachers for visual impairment and class teachers.

Outcomes

Primary outcomes

The primary outcomes of this trial relate to feasibility of a full trial. There will be four primary outcomes: 1)

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recruitment rate over 6 months, 2) retention of participants until 3 months after randomisation, 3) acceptance/usage of the allocated device, and 4) accessibility of the active intervention device.

Our recruitment target at both the site in India and the UK sites is 20 participants each over 6 months. We will consider that at definitive trial is feasible, if we enroll 90% of this figure (n=18) during this period, and/or if 100% are enrolled over 7 months. We will record the number of eligible young people declining to participate, and reasons for not wishing to take part. We will also capture whether any children drop out of the study, and why.

We will measure acceptance/usage of the allocated device using a participant diary; we will summarise usage for the electronic database as ordinal variable: 0 = no acceptance, 1 = used sometimes, 2 = used frequently. We will define success as 80% of participants in the active intervention group using the device "frequently".

Accessibility of the active intervention device will be determined by asking participants to play a touch-based game, "Piano Tiles". In this game, the player has to touch moving black tiles that move down the screen. Following an introduction to the game using the "classic" version, we will assess the young person's score in the "zen" version over 15 seconds and record the best score of three attempts. We will convert the game score to an ordinal variable for capture within the pilot database as follows: score 0-15: ordinal variable 0 = low accessibility, 16-35: 1 = medium accessibility, greater than 35: 2 = high accessibility. The protocol authors agreed on using this scoring system based on 5 children with good and with low vision playing this game; this system is at present not validated, and this pilot trial will allow us to collect data about the range of scores achieved by the population of interest.

Exploratory/secondary outcomes

In addition to the primary outcomes, which will inform a future full RCT, we will collect data on a range of measures of visual function used in healthcare settings. Specifically, we will record functional visual ability,

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as measured by Cardiff Visual Ability Questionnaire for Children (CVAQC) (11) for UK participants, and the LV Prasad Functional Vision Questionnaire (LVP-FVQII) for participants in India (12). Whilst it would be desirable to use the same instrument in both settings, differences in language and activities of daily living mean that there is no validated, universal tool that could be used both in India and in the UK.

Across all sites we will measure vision-related quality of life, using the Impact of Vision Impairment for Children (IVI_C) Questionnaire (13).

In the UK only, we will use two reading assessment tools which are available in English, but not Telugu, the local language spoken by most children in Hyderabad: 1) the Neale Analysis of Reading Ability (NARA, a test of reading accuracy, comprehension and speed) (14) (15), a tool which measures not only a visual function, but also comprehension. This is a tool commonly used in educational settings; it has only been used in one previous study with children with low vision; 2) to measure reading speed, we will use the International Reading Speed Texts (IREST) (16). NARA and IREST will be tested at baseline using the participant's current preferred LVA, and at three and six months using the allocated study device, excluding text-to-speech conversion; the assessment will be recorded as audiofile for evaluation by a masked observer.

From the participant diary and from semi-structured interviews (Supplementary Material), we will record as free text the participant's experience of independent access to the curriculum, any adverse outcomes (loss of motivation, negative peer comments) and accessibility and impact of the allocated device on the participant. At the end of the observation period, we will collect feedback from participants' school classroom teachers with regards to their impression of the impact of the allocated device on participants.

We will report the cost of the devices as cost of device and training. We will provide initial training as part of the study. For ongoing technical support, we will rely on the manufacturers' and suppliers' support helplines.

Lastly, we will record demographic data (age at study entry, gender, ethnic group), ophthalmic history (time since diagnosis of VI, underlying ophthalmic diagnosis), visual function (best corrected visual acuity for

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distance and near, monocularly and binocularly, at each timepoint, recorded in logMAR; reading acuity on the MNREAD chart with refractive correction, but without LVA (17)).

Participant timeline

Each participant will be in the study for 6 months from randomization, with assessments at baseline, three and six months. The schedule of assessments is summarized in Fig 2.

Sample size

This trial will enrol 40 students, 20 in the UK and 20 in India. A sample size of 20 is commonly used in feasibility studies. As this is the first RCT of an assistive technology for children with low vision, a formal sample size calculation was not possible; there are no data on expected recruitment and retention. We decided on a target sample size that appears achievable over a six-month period at one site in India and two sites in the UK. In addition, there are no data on effect size of assistive technologies for reading in children, and no data on effect size of conventional LVAs on any of the selected outcomes other than near and distance acuity. A sample size of 20 per site therefore appears appropriate to gather initial information.

Ethics approval and consent to participate

This work was approved by the National Research Ethics Committee North of Scotland / Grampian 15/NS/0068, and by the Sponsor's (University College London) local research ethics committee, and by the local Research Ethics Committee at the LV Prasad Institute in Hyderabad, India. Research Ethics Committee and the funders will be notified of any changes to the protocol.

All participants aged 16 and over will be asked to provide written confirmation of informed consent; in younger participants, we will obtain written consent from a parent/carer, and will invite the young person to

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sign an assent form. Children are a vulnerable population. We will ensure that children can express their feelings about taking part in the study. Whenever possible we will invite children to give written or verbal assent. If a child appears uncomfortable taking part, we will not enrol them. Only patients for whom written consent can be obtained from parents or guardians will be enrolled. If non-English speaking families wish to take part, we will use a telephone-based interpretation service to communicate.

As tablet computers are attractive to young children, it would not be fair to limit access to these devices to the intervention group only. We will therefore ask participants to return the devices at the end of the six-month study period, and issue them to the control group participants for six months. This will be after the end of the observation period, and no additional data will be collected.

Recruitment

We will identify eligible participants from low vision clinics at Moorfields in London, from students known to their local vision impairment teams in Bedford Borough and Central Bedfordshire, and the low vision clinic at the LV Prasad Eye Institute in Hyderabad.

The initial approach about the study will be conducted as follows:

1) at MEH London: a member of the clinical team providing low vision services for children and young people will tell the family about the study and gain permission to be approached by a member of the research team. Moorfields also operate an opt-out policy which allows research teams to approach patients eligible for research about research projects, but this policy clearly states that patients/families are free to decline study participation; there is no coercion.
2) at CDC Bedford: visually impaired students who are known to the VI team will first approach the young person and their family, and they are independent of the research team.
3) at LVPEI: a member of the clinical team will first approach patients, again, no coercion will be

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exerted by the research team.

Once a young person and their family have expressed an interest in taking part, we will provide verbal and written study information. An accredited paediatric optometrist who is a member of the research team (MC, VKG, RT, SB) will obtain written consent from a parent or carer, will invite children/young people to give their assent in writing or verbally.

Assignment of interventions

Allocation sequence generation and implementation

Young people who agree to take part will be randomised to receive either a tablet computer with low vision applications or standard low vision care. Allocation will be at a 1:1 ratio. At MEH London and CDC Bedford, randomisation will be prepared by the senior data manager in the Research & Development department using permuted blocks of varying sizes in the statistical program STATA; researchers will phone Moorfields R&D department after each enrolment to obtain the randomisation allocation; the senior data manger will record patient's study ID, hospital number, randomisation allocation and randomisation date on the trial randomisation log file. Randomisation for the participants at the LVPEI, India, will use a web-based tool (https://www.sealedenvelope.com), operated by an optometrist in the low vision clinic team who is not involved in the study. The researcher will contact the optometrist to obtain information about the allocated treatment as participants are enrolled.

Allocation concealment mechanisms: The study optometrist will contact the senior data manager (Moorfields) or the member of staff holding the randomisation schedule (LVP) for randomisation, so whilst allocation sequence is concealed from the research team, the allocated intervention will not be concealed. As participants attend mainstream schools, the risk of contamination by participants exchanging

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allocated equipment is low. Each participant will receive a password required to use their device and will be asked not to share it with others.

Masking

Masking of participants to the intervention will not be possible, which may cause performance bias. In order to avoid detection bias, we will mask outcome assessors to the intervention by recording reading performance as audiofiles (NARA, IREST), which will be subsequently evaluated by a masked observer. CVAQC and LVP-FVQII questionnaires will be administered by a masked observer. Diaries will be reviewed in masked fashion.

Data collection, management, and analysis

Data collection methods

Data will be collected from patients in accordance with the patient consent form, patient information sheet and the study protocol. Patients will be assigned a study number after consent prior to randomisation. This number will be used on all case report forms, questionnaires and interview material. Two separate databases will be built, one for UK and another for LVP which will capture pilot information for analysis. This will contain demographic data and information on the primary outcomes only.

Exploratory data will be captured as follows: All sites will use a standardized paper-based case report form and a standardized Microsoft Office Excel spreadsheet as database. At MEH London, MC will collect data and transfer them onto the spreadsheet; at CDC Bedford, RT and at LVP, SB and VKG will carry out data collection and transfer.

Data management (handling, processing and storage)

Data within the MEH database will be analysed by AQ. UCL as study sponsor will act as the data controller for the study. The data from LVP will remain with VKG for statistical analysis, and she will act as the data

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controller.

For the data from MEH London and CDC Bedford, ADN will process, store and dispose of all described data in accordance with all applicable legal and regulatory requirements, including the Data Protection Act 1998 and any amendments thereto. Data will be stored centrally and kept in locked, secure access filing cabinets or on password-protected NHS computers on hospital premises; this includes electronic data and case report forms, questionnaires and interview material.

For the data from the LVPEI, India, VKG will process, store and dispose of all described data in accordance with all applicable legal and regulatory requirements. Data will be stored centrally at the L V Prasad Eye Institute, Hyderabad, and kept in locked, secure access filing cabinets or on password-protected hospital computers on hospital premises; this includes electronic data and case report forms, questionnaires and interview material.

UCL and each participating site recognise that there is an obligation to archive study-related documents at the end of the study. The Chief Investigator confirms that she will archive the study master file at Moorfields Eye Hospital for the period stipulated in the protocol and in line with all relevant legal and statutory requirements. The Principal Investigator at each participating site agrees to archive his/her respective site's study documents for Moorfields Eye Hospital, the Child Development Centre Bedford and the L V Prasad Eye Institute, and in line with all relevant legal and statutory requirements.

Statistical methods:

This is a pilot RCT, and data will be used to help design a definitive study. The dataset in India and the dataset in the UK will be handled and analysed separately, as randomization methods and some of the outcomes measures (such as functional visual ability) differ between the two settings. We will use

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descriptive statistical methods only (proportions, mean/standard deviation if data are normally distributed and median/interquartile range if not), and will not make comparisons between groups.

Participant retention

This is one of the primary outcomes and detailed above. Compliance defined as usage of the allocated device will be monitored by diary. We will attempt to reduce attrition bias by staying in touch with participants throughout the study, by text messages, e-mails and phone calls. If participants wish to withdraw after they have been allocated to a treatment group, we will ask them to undergo a final assessment. We will record reasons for withdrawal on the case report form (free text). Data collected up to the point of withdrawal will be used in data analysis.

Data monitoring

The sponsor's data monitoring and auditing procedures will apply, i.e. each site will, twice a year, send the sponsor an update on the following information: delegation log, adverse event log, and deviation log. In addition, the lead site (Moorfields London) will send the sponsor a copy of the annual progress report when it is submitted to the Research Ethics Committee.

Funding

This work will be supported by a grant of £50,530 from the British Council for the Prevention of Blindness (BCPB), and by Apple (iPads and additional support for study site in India). The BCPB encouraged the authors to double the originally envisaged sample size to the current numbers. Apple Inc supports this work by providing all equipment to the site in India. Apple has not influenced the study design.

Insurance/Indemnity

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University College London holds insurance against claims from participants for harm caused by their participation in this clinical study. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, if this clinical study is being carried out in a hospital, the hospital continues to have a duty of care to the participant of the clinical study. University College London does not accept liability for any breach in the hospital's duty of care, or any negligence on the part of hospital employees. This applies whether the hospital is an NHS Trust or otherwise. Similarly, LVPEI holds a public liability policy for insurance against claims from public (patient/visitor) for harm/injury or damage caused to them or their vehicle within the premises of the hospital.

Reporting and Dissemination

We will disseminate our findings through presentations at national and international conferences, publications in scientific journals, at staff meetings, through feedback to participants. AHDN is a member of the Vision 2020/UK Vision Strategy Children with Low Vision Group, from where findings can be disseminated via the Vision2020, RNIB and Blind Children UK/Guide Dogs routes. MDC is a committee member of the International Society for Low Vision Research and Rehabilitation (ISLRR) which organizes the largest international meeting for researchers and clinicians in low vision.

Timeline, milestones and monitoring

From grant activation after ethical approval, the project will have an active participant recruitment, intervention and assessment phase of 12 months, preceded by one month for purchase of equipment and followed by two months of analysis and write-up.

Discussion

This pilot trial will be the first RCT in the field of low vision care for children and young people, bringing

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robust methodology to this research area. Besides traditional clinical measures of vision, the inclusion of educational outcomes in our study will provide highly valuable information to families and teachers of children with low vision. Education constitutes a vital component of a child/young person's "professional occupation. A study design combining clinical and educational data is therefore ideally suited to capture information relevant to young people's daily lives.

We will report feasibility outcomes which will help design a full RCT (recruitment and retention rates, which will inform sample size) and provide initial information about accessibility of the selected assistive technology devices.

Limitations

This trial has a small sample size, with 10 participants in each treatment arm in each of the two participating countries; however, in the absence of prior data, we consider this sample size acceptable to assess feasibility.

The study design reduces the risk of some, but not all types of bias. Randomisation, allocation concealment and masked assessment will reduce selection, performance and detection bias; masking of participants is not possible, so some performance and social desirability bias remain. The possibility of obtaining an iPad if taking part in the trial may influence recruitment rates; but would affect all participants equally. It is not yet known whether allocation of an iPad might have an impact on retention rates; the attractiveness of electronic devices to young people may be a source of differential bias between the study arms. In order to minimise this source of bias, those participants who have been allocated an iPad for the trial will be asked to return it at the last study visit, and those who have been allocated standard care will then have the opportunity to have an iPad for six months, without further assessments.

Strengths

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Generalizability

Particular emphasis in this study will be placed on understanding barriers to enrolment. We will document reasons for not wishing to take part, such as lack of time for research appointments, attitudes to electronic devices for use at school etc. We expect that the three study sites will encounter a variety of operational issues, some of which may differ between sites and countries.

Having research sites in a high-income and in a low-income country raises certain difficulties: quality-of-life tools need to reflect local activities of daily living, reading measurement tools need to be presented in the local language, and randomisation of participants in different time zones is challenging if relying on a central randomization facilitator.

Trial status: Participants have been enrolled between March 10 and December 6 2016, and are in follow-up until June 2017.

Trial registration: Clinicaltrials.gov NCT02798848, IRAS ID 179658, NRES reference 15/NS/0068, UCL reference 15/0570. **Funding:** British Council for the Prevention of Blindness

List of abbreviations

AT: assistive technologies BCVA: best corrected visual acuity CCTV: closed-circuit television LV: low vision LVA: low vision aid LVP: LV Prasad Institute MEH: Moorfields Eye Hospital OCR: optical character recognition R&D: research and development VA: visual acuity VI: vision impairment VLE: virtual learning environment

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Consent for publication

Not applicable

Availability of data and material

This publication relates to the trial protocol, and has not data to share. Data acquired during the trial will be shared.

Competing interests

None of the authors has competing interests to declare.

Authors' contributions

MDC, RT, VG and ADN obtained funding for this work. ADN wrote the first draft of this manuscript, which was then critically reviewed by all authors.

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Figure legends.

Figure 1. Flowchart showing planned participant flow (after Consort extension for pilot and feasibility studies [18]).

Figure 2. Schedule of enrolment, interventions, and assessments (after Spirit [19 20]).

Supplementary material

Participant diary, interview guides.

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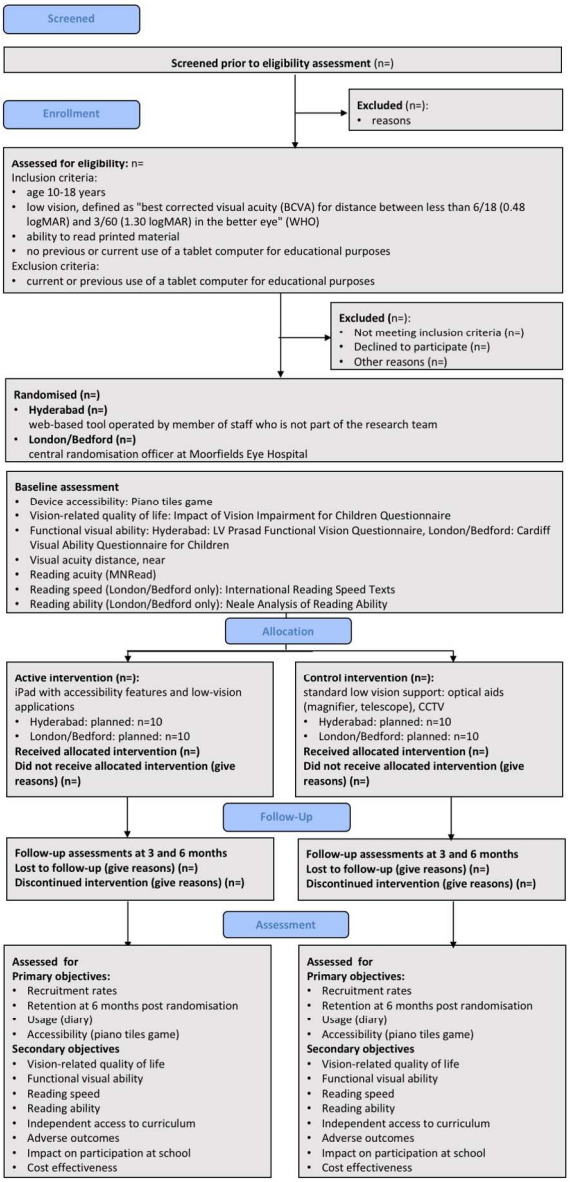

Flowchart showing planned participant flow (after Consort extension for pilot and feasibility studies 18)

375x793mm (72 x 72 DPI)

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	STUDY PERIOD				
	Enrolment	**Allocation**	**Post-allocation**		**Close-out**
TIMEPOINT**	**0**	**0**	***3 months***	***6 months***	***12 months***
ENROLMENT:					
Eligibility screen	X				
Informed consent	X				
Demographic and clinical details, near and distance visual acuity	X				
Allocation		X			
INTERVENTIONS:					
Apple iPad with applications		X	X	X	
Standard LVA (magnifiers, telescopes, CCTV)		X	X	X	
ASSESSMENTS:					
Baseline and post-allocation: Device accessibility (Piano tiles) Functional Vision questionnaire (LV Prasad, Cardiff) VR-QoL questionnaire (IVI-C) Neale Analysis of Reading Ability International Reading Speed Texts (Telugu, English) Visual acuity distance, near Reading acuity		X	X	X	
Post-allocation outcomes: As Baseline, plus: Diary review and semi-structured interview: usage, independent access to curriculum, adverse outcomes			X	X	

Figure 2. Schedule of enrolment, interventions, and assessments (after Spirit).

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Participant Diary "CREATE- Children Reading with Electronic Assistance to Educate", Version 1.1, July 14, 2015

This is a diary to help you keep track of how much you are using the device(s) that we have given you, and what you have used them for every day. You can also write down any comments that go through your mind, for example about what they have been good for, or what you thought about using them, or what other people have said.

You do not need to write lots of things every day, but **please do write down how much time you have used your device for every day.**

Thank you.

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Today's date	Number of hours you have used your devices, for …			
	Reading	Watching videos	Playing games	Other (what?)
Did you have any problems with your device(s)? Which problems?				
Any comments?				

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Today's date	Number of hours you have used your devices, for …			
	Reading	Watching videos	Playing games	Other (what?)
Did you have any problems with your device(s)? Which problems?				

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Any comments?	

Guiding questions for semistructured interviews "CREATE-Children Reading with Electronic Assistance to Educate"

Version 1.0, July 13, 2015

What do you like about the devices we have given you (this can be iPad or standard aids)?

What do you not like about these devices?

What can you do more easily when using these devices?

Where do you use the device(s) we have given you (at school, at home, elsewhere?)

What do you use them for?

Is there anything you can do with your device(s) for which you would otherwise need help from a teacher or a friend?

What other devices have you been using before?

Which device do you think works best for you?

Why?

What do your friends and classmates say about the device(s) you are using?

What do your teachers say about the device(s) you are using?

What do your parents say about the device(s) you are using?

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Teacher questionnaire, Version 1.0, August 6, 2015

Does the student use the devices in the classroom?

If yes, do they use them in every lesson?

Which activities do they use them for?

Do they use them for activities for which they would otherwise need help from a teacher or a friend?

Does the use of the device(s) integrate well into the classroom routine?

What do classmates say about the device(s)?

We would be grateful for any other comments:

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SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	abstract, 10
	2b	All items from the World Health Organization Trial Registration Data Set	
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	16
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 2,
	5b	Name and contact information for the trial sponsor	2
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	2
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	16
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5
	6b	Explanation for choice of comparators	6 (standard treatment)
Objectives	7	Specific objectives or hypotheses	6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6

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Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6, 7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	n/a
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	16
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	8-10
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Fig 1 Fig 2
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	11
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	12-13

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	13

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Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	13
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	12,13
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	14
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	14
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	16
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14,15
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	15,
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	(16)

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	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	16
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	16
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	11
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	n/a
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	13
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	uploaded protocol section 11 pages 9/10
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	20
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14/15
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	16/17
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	17
	31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	protocol uploaded

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Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

n/a.

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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CONSORT checklist of information to include when reporting a pilot trial*

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
Title and abstract			
1a	Identification as a randomised trial in the title	Identification as a pilot or feasibility randomised trial in the title	1
1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	3
Introduction			
Background and objectives:			
2a	Scientific background and explanation of rationale	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	4-5
2b	Specific objectives or hypotheses	Specific objectives or research questions for pilot trial	6
Methods			
Trial design:			
3a	Description of trial design (such as parallel, factorial) including allocation ratio	Description of pilot trial design (such as parallel, factorial) including allocation ratio	6-14
3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	n/a
Participants:			
4a	Eligibility criteria for participants		7
4b	Settings and locations where the data were collected		6-7
4c		How participants were identified and consented	12
Interventions:			
5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered		8
Outcomes:			
6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	8-11
6b	Any changes to trial outcomes after the trial commenced, with reasons	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	n/a
6c		If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	9 (~~Success~~) last paragraph

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Sample size:			
7a	How sample size was determined	Rationale for numbers in the pilot trial	11
7b	When applicable, explanation of any interim analyses and stopping guidelines		
Randomisation:			
Sequence generation:			
8a	Method used to generate the random allocation sequence		
8b	Type of randomisation; details of any restriction (such as blocking and block size)	Type of randomisation(s); details of any restriction (such as blocking and block size)	13
Allocation concealment mechanism:			
9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned		13
Implementation:			
10	Who generated the random allocation sequence, enrolled participants, and assigned participants to interventions		13
Blinding:			
11a	If done, who was blinded after assignment to interventions (eg, participants, care providers, those assessing outcomes) and how		14
11b	If relevant, description of the similarity of interventions		
Analytical methods:			
12a	Statistical methods used to compare groups for primary and secondary outcomes	Methods used to address each pilot trial objective whether qualitative or quantitative	15/16
12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Not applicable	
Results			
Participant flow (a diagram is strongly recommended):			
13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	FIG 1
13b	For each group, losses and exclusions after randomisation, together with reasons		
Recruitment:			

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14a	Dates defining the periods of recruitment and follow-up		Fig 2, abstract p19
14b	Why the trial ended or was stopped	Why the pilot trial ended or was stopped	n/a.
Baseline data:			
15	A table showing baseline demographic and clinical characteristics for each group		n/a
Numbers analysed:			
16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	n/a
Outcomes and estimation:			
17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	n/a
17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable	
Ancillary analyses:			
18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	Results of any other analyses performed that could be used to inform the future definitive trial	n/a
Harms:			
19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)		n/a
19a		If relevant, other important unintended consequences	
Discussion			
Limitations:			
20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	18
Generalisability:			
21	Generalisability (external validity, applicability) of the trial findings	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	n/a
Interpretation:			
22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	n/a
22a		Implications for progression from pilot to future definitive trial, including any proposed amendments	
Other information			

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Registration:			
23	Registration number and name of trial registry	Registration number for pilot trial and name of trial registry	abstract, 19
Protocol:			
24	Where the full trial protocol can be accessed, if available	Where the pilot trial protocol can be accessed, if available	uploaded.
Funding:			
25	Sources of funding and other support (such as supply of drugs), role of funders		p 16
26		Ethical approval or approval by research review committee, confirmed with reference number	11

*Here a pilot trial means any randomised study conducted in preparation for a future definitive RCT, where the main objective of the pilot trial is to assess feasibility.

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BMJ Open

Tablet computers versus optical aids to support education and learning in children and young people with low vision: Protocol for a pilot randomized controlled trial, CREATE – Children Reading with Electronic Assistance To Educate

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Title: Tablet computers versus optical aids to support education and learning in children and young people with low vision: Protocol for a pilot randomized controlled trial, CREATE – Children Reading with Electronic Assistance To Educate

Based on protocol version 2, November 1, 2015

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The sponsor has not influenced the design, running or any other part of this work.

Keywords

Vision, Low vision, Assistive technology, Adolescent, Child

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Abstract

Introduction: Low vision and blindness adversely affect education and independence of children and young people. New “assistive” technologies such as tablet computers can display text in enlarged font, read text out to the user, allow speech input and conversion into typed text, offer document and spreadsheet processing, and give access to wide sources of information such as the internet. Research on these devices in low vision has been limited to case series.

Methods and analysis: We will carry out a pilot randomized controlled trial (RCT) to assess the feasibility of a full RCT of assistive technologies for children/young people with low vision. We will recruit 40 students age 10-18 years in India and the UK, whom we will randomise 1:1 into two parallel groups. The active intervention will be Apple iPads; the control arm will be the local standard low-vision aid care. Primary outcomes will be acceptance/usage, accessibility of the device and trial feasibility measures (time to recruit children, loss to follow up). Exploratory outcomes will be validated measures of vision-related quality of life for children/young people as well as validated measures of reading and educational outcomes. In addition, we will carry out semi-structured interviews with the participants and their teachers.

Ethics and dissemination: NRES reference 15/NS/0068; dissemination is planned via healthcare and education sector conferences and publications, as well as via patient support organisations.

Trial registration: Clinicaltrials.gov NCT02798848, IRAS ID 179658, UCL reference 15/0570.

Funding: British Council for the Prevention of Blindness

Strengths - Enrolment in different settings, pragmatically exploring feasibility

- low selection, performance and detection bias

Limitations: - small sample size

- performance and social desirability bias (masking of participants not possible)

- possible differential bias between study arms (attractiveness of active intervention)

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Introduction

People are considered to have "low vision" when their corrected visual acuity (VA) is poorer than 6/18 in their better eye, or their visual field is less than 10 degrees from the point of fixation, but they use, or are potentially able to use, vision for the planning and/or execution of a task [1]. There is an overlap with the definitions of visual impairment and severe visual impairment/blindness. Low vision affects almost 3 million children worldwide [2 3]. It adversely affects educational and employment opportunities, causing economic hardship in adult life [4 5]. Early assessment, provision of low vision aids (LVAs) and training in their use are essential to improve functional vision and to allow children to fully participate in education and improve their quality of life (QoL).

In recent years, LVAs have been complemented by "assistive technologies" (AT). These include electronic vision enhancement devices such as closed circuit video magnifiers (CCTV), computer screen reading software, digital audio books, periodicals and text which can be accessed via computers, mobile phones, and tablet computers. Assistive technology may enhance reading and writing skills, as well as communication with the world on an equal basis, thereby improving the quality of life of people with low vision and facilitating the learning process [6].

Teachers, parents, and young people with low vision report limited use of prescribed LVAs and other assistive technology devices, usually for fear of "standing out". Electronic devices can have other limitations including a lack of portability, poor integration with school information technology networks, and limitations of either input or output functions.

Tablet computers may help overcome many of these problems, as they are portable, capable of running a wide range of software and of accessing wireless networks. More importantly, acceptability by young people may be high. Numerous applications are available, such as screen magnifiers, optical character recognition and text-to-speech conversion. All

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manufacturers provide “accessibility features”. The Apple iPad, recommended by low-vision support charities such as the Royal National Institute for Blind People and the Royal London Society for the Blind, increases reading speed in adults with low vision [7]and is used by many people with low vision [8].

Tablet computers are of considerably lower cost (around £400-1,600 per student) than current standard classroom technology, such as CCTV (which can cost up to £6,400 with distance and near camera, per student). Tablet computers offer the additional advantages of direct access to school intranets, social acceptability, and word document and spreadsheet processing. Additionally, the price of tablet computers is likely to fall, whereas CCTVs has remained high.

In the UK, support funding for children and young people with visual impairment (VI) in Local Authority maintained settings has traditionally been administered by their local authority. There is increasingly a shift of funding streams, for example, children with VI may attend educational settings which are not funded or maintained by the Local Authority; or individual funding may be agreed with the family (“self-directed support”). Robust information about the performance of different devices is vitally important not only for educational settings, but also for families and carers.

We have carried out two systematic Cochrane reviews of the paediatric low-vision literature, and have found that to date, no clinical trials of AT for young people with low vision have been conducted [9 10]. Instead, the literature is limited to small non-randomised case series and cohort studies, mostly of optical devices. Informal discussions with young people with VI, their families and teachers indicate that those who have access to tablet computers such as Apple iPads find their accessibility features very useful, and would support research comparing this AT with conventional LVAs.

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Methods and analysis

Our hypothesis is that tablet computer-based AT may have high acceptability and usage by children and young people with low vision, and may improve their functional vision (FV), vision-related quality of life (VRQoL) and access to education. As no preliminary data on trial feasibility are available, we will carry out a pilot study to assess whether or not a definitive trial exploring this issue is feasible.

Primary objective

The principal research question is: "Is it feasible to recruit young people with low vision into a randomised controlled trial testing the effect of electronic assistive technologies on reading, educational and quality of life outcome measures?"

Secondary research questions

1) Is the active intervention (tablet computer) acceptable to young people, their families/carers, and their teachers?

2) Is the active intervention accessible, and do participants use it?

3) Estimate vision-related quality of life measures, functional vision measures, and reading and educational outcome measures by intervention group at 6 months

4) Have there been any adverse events (loss of motivation, negative peer comments) about using the assistive technology?

5) What are the costs associated with the active intervention?

Trial design

This is a parallel 1:1 two arm pilot RCT; the experimental intervention will be an Apple iPad tablet computer with low-vision-applications, and the control intervention will consist of the

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conventional low-vision support as per standard clinical care, which includes optical LVA and/or CCTV.

Study setting

There will be three recruitment sites, one in India (L V Prasad Eye Institute [LVPEI], Hyderabad, Telangana - Meera and L B Deshpande Centre for Sight Enhancement, a tertiary eye care hospital) and two in the UK: The Child Development Centre in Bedford (a multidisciplinary community health, education and social care facility for children with developmental needs and disabilities) and the Low Vision Clinic for children and young people at Moorfields Eye Hospital (a tertiary eye care facility in London). The decision to have two very different settings reflects the study funders' aim to provide people in low-income countries with equal access to innovation, and to shorten the timescale of implementation of novel approaches in low-income settings.

Inclusion criteria

We will include young people age 10-18 years with low vision, defined as "best corrected visual acuity (BCVA) for distance between less than 6/18 (0.48 logMAR) and 3/60 (1.30 logMAR) in the better eye" (WHO), who are able to read printed material and who are not currently using, and have not previously used, tablet computer for educational purposes (Fig. 1). We will include students who have access to a tablet computer already, but do not use it for educational purposes. We will include students who use a laptop. We will also include students who use or have previously used optical low-vision aids such as magnifiers, telescopes and CCTV systems.

Exclusion criteria

Young people who are currently using or are prior users of a tablet computer for educational purposes (at school or frequently for homework) will be excluded. We accept that many videos and games children watch on tablet computers can be seen as educational, and that many

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children will use a tablet computer occasionally for research for homework. We will include young people using a tablet computer in this way.

Should participants in the control group receive a tablet computer from their local visual impairment team, from their educational setting, or if they start taking their own tablet computer to school, they will be removed from the trial and no further data collection will take place.

Near visual acuity equivalent to 6/18 (0.48 logMAR) or better will not be an exclusion criterion, as even though students may perform well on a near acuity test, their reading acuity may be less than the near acuity measured in a clinical setting. Furthermore, as functional reading acuity can gradually reduce over the course of the day, there may be an increase in the need for optical magnification towards the end of the day, and when completing homework. Figure 1 summarises the design of the trial; each of the trial aspects is described in detail below.

Interventions

All participants recruited in India and London site will receive a comprehensive low vision assessment with an optometrist, including **the prescription and supply of** optimal refractive correction, tints, and optical devices (magnifiers, telescopes); discussion and demonstration of electronic magnifiers, signposting to appropriate services, and liaison with teachers for visual impairment and class teachers.

The **active Intervention** will be the use of a tablet computer (Apple iPad) for educational purposes at school and at home. The device will run word processing, spreadsheet and slide presentation files (Microsoft Office for iPad). These will allow students to import documents from the school's learning environment onto their device, work on them, and export them back to the teacher. Users will be given information and instruction on Voiceover (text-to-speech),

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magnification and contrast settings in the iOS software. In addition, we will install the video magnifier, colour identifying and image recognition application "ViaOpta Daily". The UK devices will have WiFi enabled to access school wireless networks. Additionally those in India will have wireless data (3G) connectivity.

None of these applications is a medical device; they therefore do not require CE marking (confirmed by MHRA). We will activate the device accessibility features and install the applications before participants receive the devices. In London and India, study optometrists will train participants in the use of devices, features and applications. In Bedford, the team for visually impaired pupils will support this training. We envisage an initial training session of two hours in the first week, followed by telephone support or follow up visits to the setting if required. For participants recruited in London, each participant's teacher for vision impaired will be informed of their inclusion in this study. Letters will be sent to the class teacher, teacher for vision impaired, and school special needs coordinator (SENCo) requesting that the young person is allowed to use their device in the classroom.

In India, participants were provided with training in use of the devices and iPad at the low vision rehabilitation centre. Additional support was provided over phone to children who faced some difficulty with using the iPad initially.

The **control intervention** will consist of the comprehensive low vision assessment only. Due to differences in the recruitment route at Bedford, participants in the control group at Bedford will not be reassessed but will continue with their current spectacles and low vision devices, and will continue to be monitored by the VI team.

Outcomes

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Primary outcomes

The primary outcomes of this trial relate to feasibility of a full trial. There will be four primary outcomes: 1) recruitment rate over 6 months, 2) retention of participants until 3 months after randomisation, 3) acceptance/usage of the allocated device, and 4) accessibility of the active intervention device.

Our recruitment target at both the site in India and the UK sites is 20 participants each over 6 months. We will consider that at definitive trial is feasible, if we enroll 90% of this figure (n=18) during this period, and/or if 100% are enrolled over 7 months. We will record the number of eligible young people declining to participate, and reasons for not wishing to take part. We will also capture whether any children drop out of the study, and why.

We will measure acceptance/usage of the allocated device using a participant diary; we will summarise usage for the electronic database as ordinal variable: 0 = no acceptance, 1 = used sometimes, 2 = used frequently. We will define success as 80% of participants in the active intervention group using the device "frequently".

Accessibility of the active intervention device will be determined by asking participants to play a touch-based game, "Piano Tiles". In this game, the player has to touch moving black tiles that move down the screen. Following an introduction to the game using the "classic" version, we will assess the young person's score in the "zen" version over 15 seconds and record the best score of three attempts. We will convert the game score to an ordinal variable for capture within the pilot database as follows: score 0-15: ordinal variable 0 = low accessibility, 16-35: 1 = medium accessibility, greater than 35: 2 = high accessibility. The protocol authors agreed on using this scoring system based on 5 children with good and with low vision playing this game; this system is at present not validated, and this pilot trial will allow us to collect data about the range of scores achieved by the population of interest.

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Exploratory/secondary outcomes

In addition to the primary outcomes, which will inform a future full RCT, we will collect data on a range of measures of visual function used in healthcare settings. Specifically, we will record functional visual ability, as measured by Cardiff Visual Ability Questionnaire for Children (CVAQC) [11] for UK participants, and the LV Prasad Functional Vision Questionnaire (LVP-FVQII) for participants in India [12]. Whilst it would be desirable to use the same instrument in both settings, differences in language and activities of daily living mean that there is no validated, universal tool that could be used both in India and in the UK.

Across all sites we will measure vision-related quality of life, using the Impact of Vision Impairment for Children (IVI_C) Questionnaire [13].

In the UK only, we will use three reading assessment tools which are available in English, but not Telugu, the local language spoken by most children in Hyderabad: 1) the Neale Analysis of Reading Ability (NARA, a test of reading accuracy, comprehension and speed) [14 15], a tool which measures not only a visual function, but also comprehension. This is a tool commonly used in educational settings; it has only been used in one previous study with children with low vision; 2) to measure reading speed, we will use the International Reading Speed Texts (IReST) [16]; 3) to measure peak reading speed, near visual acuity and critical print size, the MNREAD test [17]. NARA and IREST will be tested at baseline using the participant's current preferred LVA, and at three and six months using the allocated study device, excluding text-to-speech conversion; the assessment will be recorded as audiofile for evaluation by a masked observer. MNREAD will be performed using spectacle correction only.

From the participant diary and from semi-structured interviews (Supplementary Material), we will record as free text the participant's experience of independent access to the curriculum, any adverse outcomes (loss of motivation, negative peer comments) and accessibility and impact of

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the allocated device on the participant. At the end of the observation period, we will collect feedback from participants' teachers with regards to their impression of the impact of the allocated device on participants. We will report the cost of the devices as cost of device and training. We will provide initial training as part of the study. For ongoing technical support, we will rely on the manufacturers' and suppliers' support helplines.

Lastly, we will record demographic data (age at study entry, gender, ethnic group), ophthalmic history (time since diagnosis of VI, underlying ophthalmic diagnosis), visual function (best corrected visual acuity for distance and near, monocularly and binocularly, at each timepoint, recorded in logMAR; reading acuity on the MNREAD chart with refractive correction, but without LVA [18]).

Participant timeline

Each participant will be in the study for 6 months from randomisation, with assessments at baseline, three and six months. The schedule of assessments is summarized in Fig 2.

Sample size

This trial will enrol 40 students, 20 in the UK and 20 in India. A sample size of 20 is commonly used in feasibility studies. As this is the first RCT of an assistive technology for children with low vision, a formal sample size calculation was not possible; there are no data on expected recruitment and retention. We decided on a target sample size that appears achievable over a six-month period at one site in India and two sites in the UK. In addition, there are no data on effect size of assistive technologies for reading in children, and no data on effect size of conventional LVAs on any of the selected outcomes other than near and distance acuity. A sample size of 20 per site therefore appears appropriate to gather initial information.

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Recruitment

We will identify eligible participants from low vision clinics at Moorfields in London, from students known to their local vision impairment teams in Bedford Borough and Central Bedfordshire, and the low vision clinic at the LV Prasad Eye Institute in Hyderabad.

The initial approach about the study will be conducted as follows:

1) at MEH London: a member of the clinical team providing low vision services for children and young people will tell the family about the study and gain permission to be approached by a member of the research team. Moorfields also operate an opt-out policy which allows research teams to approach patients eligible for research about research projects. This policy clearly states that patients/families are free to decline study participation; there is no coercion.
2) at CDC Bedford: Students known to the Bedfordshire teachers for visually impaired students will be approached, along with their family.
3) at LVPEI: a member of the clinical team will first approach patients and their family.

Once a young person and their family have expressed an interest in taking part, we will provide verbal and written study information. An accredited paediatric optometrist who is a member of the research team (MC, VKG, RT, SB) will obtain written consent from a parent or carer, and will invite children/young people to give their assent in writing or verbally.

Assignment of interventions

Allocation sequence generation and implementation

Young people who agree to take part will be randomised to receive either a tablet computer with low vision applications or standard low vision care. Allocation will be at a 1:1 ratio. At MEH London and CDC Bedford, randomisation will be prepared by the senior data manager in the Research & Development department using permuted blocks of varying sizes in the statistical

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program STATA; researchers will phone Moorfields R&D department after each enrolment to obtain the randomisation allocation; the senior data manger will record patient's study ID, hospital number, randomisation allocation and randomisation date on the trial randomisation log file. Randomisation for the participants at the LVPEI, India, will use a web-based tool (https://www.sealedenvelope.com), operated by an optometrist in the low vision clinic team who is not involved in the study. The researcher will contact the optometrist to obtain information about the allocated treatment as participants are enrolled.

Allocation concealment mechanisms

The study optometrist will contact the senior data manager (Moorfields) or the member of staff holding the randomisation schedule (LVP) for randomisation, so whilst allocation sequence is concealed from the research team, the allocated intervention will not be concealed. As participants attend a wide range of schools, the risk of contamination by participants exchanging allocated equipment is low. Each participant will receive a password required to use their device and will be asked not to share it with others.

Masking

Masking of participants to the intervention will not be possible, which may cause performance bias. In order to avoid detection bias, we will mask outcome assessors to the intervention by recording reading performance as audiofiles (NARA, IREST), which will be subsequently evaluated by a masked observer. CVAQC and LVP-FVQII questionnaires will be administered by a masked observer. Diaries will be reviewed in masked fashion.

Data collection, management, and analysis

Data collection methods

Data will be collected from patients in accordance with the patient consent form, patient

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information sheet and the study protocol. Patients will be assigned a study number after consent prior to randomisation. This number will be used on all case report forms, questionnaires and interview material. Two separate databases will be built, one for UK and another for LVP which will capture pilot information for analysis. This will contain demographic data and information on the primary outcomes only.

Exploratory data will be captured as follows: All sites will use a standardized paper-based case report form and a standardized Microsoft Office Excel spreadsheet as database. At MEH London, MC will collect data and transfer them onto the spreadsheet; at CDC Bedford, RT and at LVP, SB and VKG will carry out data collection and transfer.

Data management (handling, processing and storage)

Data within the MEH database will be analysed by AQ, who will not meet the participants or be involved in data collection. UCL as study sponsor will act as the data controller for the study. The data from LVP will remain with VKG for statistical analysis, and she will act as the data controller.

For the data from MEH London and CDC Bedford, ADN will process, store and dispose of all described data in accordance with all applicable legal and regulatory requirements, including the Data Protection Act 1998 and any amendments thereto. Data will be stored centrally and kept in locked, secure access filing cabinets or on password-protected NHS computers on hospital premises; this includes electronic data and case report forms, questionnaires and interview material.

For the data from the LVPEI, India, VKG will process, store and dispose of all described data in accordance with all applicable legal and regulatory requirements. Data will be stored centrally at the L V Prasad Eye Institute, Hyderabad, and kept in locked, secure access filing cabinets or on password-protected hospital computers on hospital premises; this includes electronic data and

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case report forms, questionnaires and interview material.

UCL and each participating site recognise that there is an obligation to archive study-related documents at the end of the study. The Chief Investigator confirms that she will archive the study master file at Moorfields Eye Hospital for the period stipulated in the protocol and in line with all relevant legal and statutory requirements. The Principal Investigator at each participating site agrees to archive his/her respective site's study documents for Moorfields Eye Hospital, the Child Development Centre Bedford and the L V Prasad Eye Institute, and in line with all relevant legal and statutory requirements.

Statistical methods

This is a pilot RCT, and data will be used to help design a definitive study. The dataset in India and the dataset in the UK will be handled and analysed separately, as randomisation methods and some of the outcomes measures (such as functional visual ability) differ between the two settings. We will use descriptive statistical methods only (proportions, mean/standard deviation if data are normally distributed and median/interquartile range if not), and will not make comparisons between groups.

Participant retention

This is one of the primary outcomes and detailed above. Compliance defined as usage of the allocated device will be monitored by diary. We will attempt to reduce attrition bias by staying in touch with participants throughout the study, by text messages, e-mails and phone calls, and (in Bedford) visits to the educational setting. If participants wish to withdraw after they have been allocated to a treatment group, we will ask them to undergo a final assessment. We will record reasons for withdrawal on the case report form (free text). Data collected up to the point of withdrawal will be used in data analysis.

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Data monitoring

The sponsor's data monitoring and auditing procedures will apply, i.e. each site will, twice a year, send the sponsor an update on the following information: delegation log, adverse event log, and deviation log. In addition, the lead site (Moorfields London) will send the sponsor a copy of the annual progress report when it is submitted to the Research Ethics Committee.

Funding

This work will be supported by a grant of £50,530 from the British Council for the Prevention of Blindness (BCPB), and by Apple (iPads and additional support for study site in India). The BCPB encouraged the authors to double the originally envisaged sample size to the current numbers. Apple Inc supports this work by providing all equipment to the site in India. Apple has not influenced the study design.

Insurance/Indemnity

University College London holds insurance against claims from participants for harm caused by their participation in this clinical study. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, if this clinical study is being carried out in a hospital, the hospital continues to have a duty of care to the participant of the clinical study. University College London does not accept liability for any breach in the hospital's duty of care, or any negligence on the part of hospital employees. This applies whether the hospital is an NHS Trust or otherwise. Similarly, LVPEI holds a public liability policy for insurance against claims from public (patient/visitor) for harm/injury or damage caused to them or their vehicle within the premises of the hospital.

Timeline, milestones and monitoring

From grant activation after ethical approval, the project will have an active participant recruitment, intervention and assessment phase of 12 months, preceded by one month for

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purchase of equipment and followed by two months of analysis and write-up.

Discussion

This pilot trial will be the first RCT in the field of low vision care for children and young people, bringing robust methodology to this research area. Besides traditional clinical measures of vision, the inclusion of educational outcomes in our study will provide highly valuable information to families and teachers of children with low vision. Education constitutes a vital component of a child/young person's "professional occupation. A study design combining clinical and educational data is therefore ideally suited to capture information relevant to young people's daily lives.

We will report feasibility outcomes which will help design a full RCT (recruitment and retention rates, which will inform sample size) and provide initial information about accessibility of the selected assistive technology devices.

Limitations

This trial has a small sample size, with 10 participants in each treatment arm in each of the two participating countries; however, in the absence of prior data, we consider this sample size acceptable to assess feasibility.

Our age range is deliberately broad, from 10-18 years. There are likely to be significant differences between young people of 10 years and those of 18 years in terms of complexity of schoolwork, volume of homework, and acceptability of using assistive technology. We have not attempted to balance the age of participants in each group but suggest this is considered in future trials of this nature.

Our geographical spread is wide and the levels of support already received by children differ greatly between the UK and India. Although there are teachers for the visually impaired (TVI) in India, they are typically employed in special schools for the blind and are well versed with

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Braille. There is not an analogous support system for children with low vision in mainstream schools. However, most teachers in these schools encourage children to use the prescribed low vision devices and make the required arrangements in the classroom, for example, seating young people with visual impairment in the first row and allowing extra time to copy from the board.

The study design reduces the risk of some, but not all types of bias. Randomisation, allocation concealment and masked assessment will reduce selection, performance and detection bias; masking of participants is not possible, so some performance and social desirability bias remain. The possibility of obtaining an iPad if taking part in the trial may influence recruitment rates, but this would affect all participants equally. It is not yet known whether allocation of an iPad might have an impact on retention rates; the attractiveness of electronic devices to young people may be a source of differential bias between the study arms. In order to minimise this source of bias, those participants who have been allocated an iPad for the trial will be asked to return it at the last study visit, and those who have been allocated standard care will then have the opportunity to have an iPad for six months, without further assessments. We will analyse drop-outs in each group and this may affect the design of any future studies we perform in this area: for example, we may ensure each participant receives a device to keep at some stage.

We rely on self-report for measuring device use, which may be a source of error. We initially considered using tracking software to determine the time for which devices were used (and what they were being used for) but felt there were significant practical, ethical, and privacy concerns when doing this.

Strengths

Generalizability

Particular emphasis in this study will be placed on understanding barriers to enrolment. We will document reasons for not wishing to take part, such as lack of time for research appointments,

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attitudes to electronic devices for use at school etc. We expect that the three study sites will encounter a variety of operational issues, some of which may differ between sites and countries.

Having research sites in a high-income and in a low-income country raises certain difficulties: quality-of-life tools need to reflect local activities of daily living, reading measurement tools need to be presented in the local language, and randomisation of participants in different time zones is challenging if relying on a central randomisation facilitator.

Ethics and dissemination

Ethics

This work was approved by the National Research Ethics Committee North of Scotland / Grampian 15/NS/0068, and by the Sponsor's (University College London) local research ethics committee, and by the local Research Ethics Committee at the LV Prasad Institute in Hyderabad, India. Research Ethics Committee and the funders will be notified of any changes to the protocol.

All participants aged 16 and over will be asked to provide written confirmation of informed consent; in younger participants, we will obtain written consent from a parent/carer, and will invite the young person to sign an assent form. Children are a vulnerable population. We will ensure that children can express their feelings about taking part in the study. Whenever possible we will invite children to give written or verbal assent. If a child appears uncomfortable taking part, we will not enrol them. Only patients for whom written consent can be obtained from parents or guardians will be enrolled. If non-English speaking families wish to take part, we will use a telephone-based interpretation service to communicate.

As tablet computers are attractive to young children, it would not be fair to limit access to these

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devices to the intervention group only. We will therefore ask participants to return the devices at the end of the six-month study period, and issue them to the control group participants for six months. This will be after the end of the observation period, and no additional data will be collected.

Reporting and Dissemination

We will disseminate our findings through presentations at national and international conferences, publications in scientific journals, at staff meetings, through feedback to participants. AHDN is a member of the Vision 2020/UK Vision Strategy Children with Low Vision Group, from where findings can be disseminated via the Vision2020, RNIB and Blind Children UK/Guide Dogs routes. MDC is a committee member of the International Society for Low Vision Research and Rehabilitation (ISLRR) which organizes the largest international meeting for researchers and clinicians in low vision.

Trial registration: Clinicaltrials.gov NCT02798848, IRAS ID 179658, NRES reference 15/NS/0068, UCL reference 15/0570. **Funding:** British Council for the Prevention of Blindness

List of abbreviations

AT: assistive technologies BCVA: best corrected visual acuity CCTV: closed-circuit television LV: low vision LVA: low vision aid LVP: LV Prasad Institute MEH: Moorfields Eye Hospital OCR: optical character recognition R&D: research and development VA: visual acuity VI: vision impairment VLE: virtual learning environment

Consent for publication

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Not applicable

Availability of data and material

This publication relates to the trial protocol, and has not data to share. Data acquired during the trial will be shared.

Competing interests

None of the authors has competing interests to declare.

Authors' contributions

MDC, RT, VG and ADN obtained funding for this work. ADN wrote the first draft of this manuscript, which was then critically reviewed by all authors.

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Figure legends.

Figure 1. Flowchart showing planned participant flow (after Consort extension for pilot and feasibility studies [19]).

Figure 2. Schedule of enrolment, interventions, and assessments (after Spirit [20 21]).

Supplementary material

Participant diary, interview guides.

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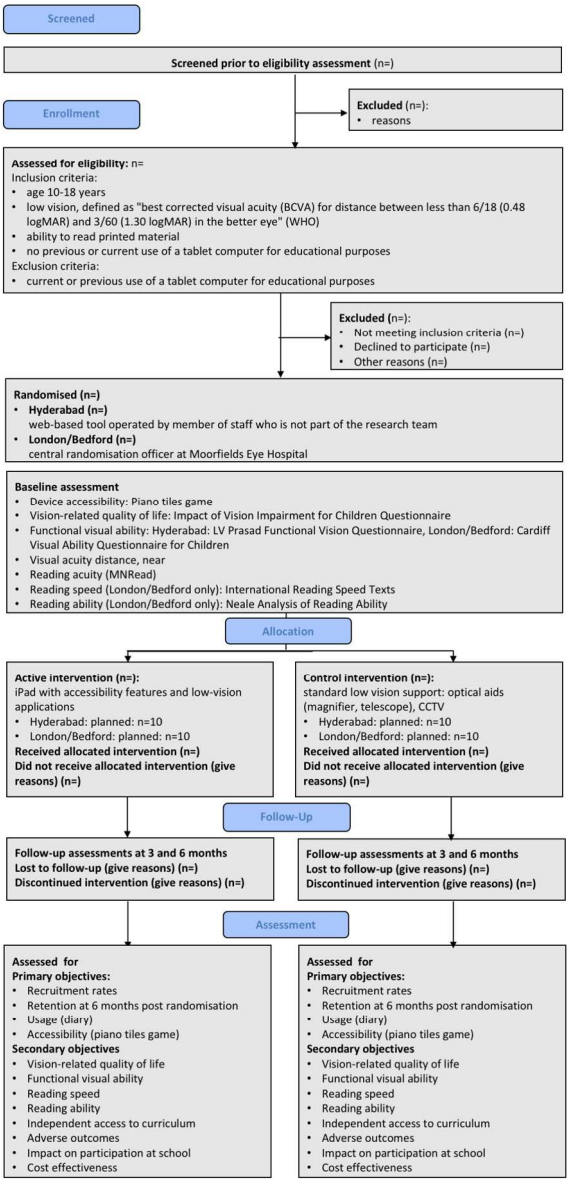

Figure 1. Flowchart showing planned participant flow (after Consort extension for pilot and feasibility studies 19).

375x793mm (72 x 72 DPI)

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	STUDY PERIOD				
	Enrolment	Allocation	Post-allocation		Close-out
TIMEPOINT**	0	0	3 months	6 months	12 months
ENROLMENT:					
Eligibility screen	X				
Informed consent	X				
Demographic and clinical details, near and distance visual acuity	X				
Allocation		X			
INTERVENTIONS:					
Apple iPad with applications		X	X	X	
Standard LVA (magnifiers, telescopes, CCTV)		X	X	X	
ASSESSMENTS:					
Baseline and post-allocation: Device accessibility (Piano tiles) Functional Vision questionnaire (LV Prasad, Cardiff) VR-QoL questionnaire (IVI-C) Neale Analysis of Reading Ability International Reading Speed Texts (Telugu, English) Visual acuity distance, near Reading acuity		X	X	X	
Post-allocation outcomes: As Baseline, plus: Diary review and semi-structured interview: usage, independent access to curriculum, adverse outcomes			X	X	

Figure 2. Schedule of enrolment, interventions, and assessments (after Spirit 20 21).

43x41mm (300 x 300 DPI)

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Participant Diary "CREATE- Children Reading with Electronic Assistance to Educate", Version 1.1, July 14, 2015

This is a diary to help you keep track of how much you are using the device(s) that we have given you, and what you have used them for every day. You can also write down any comments that go through your mind, for example about what they have been good for, or what you thought about using them, or what other people have said.

You do not need to write lots of things every day, but **please do write down how much time you have used your device for every day.**

Thank you.

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Today's date	Number of hours you have used your devices, for …			
	Reading	Watching videos	Playing games	Other (what?)
Did you have any problems with your device(s)? Which problems?				
Any comments?				

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Today's date	Number of hours you have used your devices, for …			
	Reading	Watching videos	Playing games	Other (what?)
Did you have any problems with your device(s)? Which problems?				

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Any comments?	

Guiding questions for semistructured interviews "CREATE-Children Reading with Electronic Assistance to Educate"

Version 1.0, July 13, 2015

What do you like about the devices we have given you (this can be iPad or standard aids)?

What do you not like about these devices?

What can you do more easily when using these devices?

Where do you use the device(s) we have given you (at school, at home, elsewhere?)

What do you use them for?

Is there anything you can do with your device(s) for which you would otherwise need help from a teacher or a friend?

What other devices have you been using before?

Which device do you think works best for you?

Why?

What do your friends and classmates say about the device(s) you are using?

What do your teachers say about the device(s) you are using?

What do your parents say about the device(s) you are using?

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Teacher questionnaire, Version 1.0, August 6, 2015

Does the student use the devices in the classroom?

If yes, do they use them in every lesson?

Which activities do they use them for?

Do they use them for activities for which they would otherwise need help from a teacher or a friend?

Does the use of the device(s) integrate well into the classroom routine?

What do classmates say about the device(s)?

We would be grateful for any other comments:

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SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	___1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	___3_____
	2b	All items from the World Health Organization Trial Registration Data Set	_____
Protocol version	3	Date and version identifier	___1_____
Funding	4	Sources and types of financial, material, and other support	___3_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	___1_____
	5b	Name and contact information for the trial sponsor	___2_____
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	___2_____
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	___n/a_____

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Introduction

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5
	6b	Explanation for choice of comparators	6/7
Objectives	7	Specific objectives or hypotheses	6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8/9
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	8
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	16
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	7
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9/10
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	12

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Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	12
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	13
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	13
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	13
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	13
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	13
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	14/15
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	16

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Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	15
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	16
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	n/a
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	n/a
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	17
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	17
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	17
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	20
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	

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Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	_____20_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	_____n/a_____
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	_uploaded protocol section 11_
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	_____22_____
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	_____15/16___
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	_____17_____
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	____ 21_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	_____n/a_____
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	____ n/a_____
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	____n/a_____
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	____n/a_____

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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CONSORT checklist of information to include when reporting a pilot trial*

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
Title and abstract			
1a	Identification as a randomised trial in the title	Identification as a pilot or feasibility randomised trial in the title	1
1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	3
Introduction			
Background and objectives:			
2a	Scientific background and explanation of rationale	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	4-5
2b	Specific objectives or hypotheses	Specific objectives or research questions for pilot trial	6
Methods			
Trial design:			
3a	Description of trial design (such as parallel, factorial) including allocation ratio	Description of pilot trial design (such as parallel, factorial) including allocation ratio	6-14
3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	n/a
Participants:			
4a	Eligibility criteria for participants		7
4b	Settings and locations where the data were collected		6-7
4c		How participants were identified and consented	12
Interventions:			
5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered		8
Outcomes:			
6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	8-11
6b	Any changes to trial outcomes after the trial commenced, with reasons	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	n/a
6c		If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	9 (~~Success~~ last paragraph)

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Sample size:			
7a	How sample size was determined	Rationale for numbers in the pilot trial	11
7b	When applicable, explanation of any interim analyses and stopping guidelines		
Randomisation:			
Sequence generation:			
8a	Method used to generate the random allocation sequence		
8b	Type of randomisation; details of any restriction (such as blocking and block size)	Type of randomisation(s); details of any restriction (such as blocking and block size)	13
Allocation concealment mechanism:			
9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned		13
Implementation:			
10	Who generated the random allocation sequence, enrolled participants, and assigned participants to interventions		13
Blinding:			
11a	If done, who was blinded after assignment to interventions (eg, participants, care providers, those assessing outcomes) and how		14
11b	If relevant, description of the similarity of interventions		
Analytical methods:			
12a	Statistical methods used to compare groups for primary and secondary outcomes	Methods used to address each pilot trial objective whether qualitative or quantitative	15/16
12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Not applicable	
Results			
Participant flow (a diagram is strongly recommended):			
13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	FIG 1
13b	For each group, losses and exclusions after randomisation, together with reasons		
Recruitment:			

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14a	Dates defining the periods of recruitment and follow-up		Fig 2, abstract p19
14b	Why the trial ended or was stopped	Why the pilot trial ended or was stopped	n/a.
Baseline data:			
15	A table showing baseline demographic and clinical characteristics for each group		n/a
Numbers analysed:			
16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	n/a
Outcomes and estimation:			
17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	n/a
17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable	
Ancillary analyses:			
18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	Results of any other analyses performed that could be used to inform the future definitive trial	n/a
Harms:			
19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)		n/a
19a		If relevant, other important unintended consequences	
Discussion			
Limitations:			
20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	18
Generalisability:			
21	Generalisability (external validity, applicability) of the trial findings	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	n/a
Interpretation:			
22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	n/a
22a		Implications for progression from pilot to future definitive trial, including any proposed amendments	
Other information			

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Registration:			
23	Registration number and name of trial registry	Registration number for pilot trial and name of trial registry	abstract, 19
Protocol:			
24	Where the full trial protocol can be accessed, if available	Where the pilot trial protocol can be accessed, if available	uploaded.
Funding:			
25	Sources of funding and other support (such as supply of drugs), role of funders		p 16
26		Ethical approval or approval by research review committee, confirmed with reference number	11

*Here a pilot trial means any randomised study conducted in preparation for a future definitive RCT, where the main objective of the pilot trial is to assess feasibility.

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