PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	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
AUTHORS	Crossland, Michael; Thomas, Rachel; Unwin, Hilary; Bharani, Seelam; Gothwal, Vijaya; Quartilho, Ana; Bunce, Catey; Dahlmann-Noor, Annegret

VERSION 1 - REVIEW

REVIEWER	Ahalya Subramanian Division of Optometry and Visual Science, City, University of London, United Kingdom
REVIEW RETURNED	03-Feb-2017

GENERAL COMMENTS	I enjoyed reading the paper, it is well written and in an area that is very under-researched so it's great to see an RCT that is well designed and thought through. The collaboration between India and the UK is a definite plus and a big undertaking and the authors are to be congratulated for attempting to conduct a trial in two diverse locations. It would help to understand why the age group of 10-18 was chosen. A 10 year old is very different to an 18 year old and the 'anxieties' faced and 'educational' challenges can be very different. For example a 15-16 year old will be doing their GCSEs/10th standard exams and the educational challenges they face are very different to a 10 year old in grade 5/standard 6 student for example. How will you ensure that you get an even spread of participants across all age points. How do you define 'educational' purposes? There really is a very fine line between what might be considered for 'leisure' and what may be considered 'educational'. For example many children play video games that have both an educational and leisure element. How does this impact your inclusion/exclusion criteria? It isn't particularly clear from the paper that all participants will receive a standard eye exam including an up to date prescription. One group will then get a specially modified iPad and the other will get conventional low vision care. Perhaps this can be made clearer. It became obvious to me from the appendix (protocol) but not actually whilst reading the paper. What mechanisms do you have in place to ensure that participants will return iPads. Also it is not clear whether the iPads will be wifi/3G enabled, which would increase what they can potentially be used for. Please clarify. How will you ensure that the diaries are filled in accurately? Please clarify. This is more of an ethical question (although I note you already have

	ethical approval and this therefore is a mute point), but what would you do if the child did not want to return the iPad because they loved it so much? There are some differences between the paper and the protocol in the appendix. For example the AME (Sight App) is mentioned in the protocol but the ViaOptaDaily app is mentioned in the paper. The protocol mentions MNREAD, there is no mention in the paper. Could you clarify why this is the case? Would it be worthwhile adding that statistical data analysis will be carried out by CB (not involved in any way with actual data collection etc.)- this is clear in the protocol but not in the paper Is 6/18 not 0.50LogMAR not 0.48LogMAR? Page 6 line 5 says that the cost of CCTVs hasn't changed in 20 years, the protocol says 10 years. Be consistent.

REVIEWER	Woodhouse, Margaret Cardiff University UK
REVIEW RETURNED	15-Feb-2017

GENERAL COMMENTS	This is comprehensive and well-written description of a pilot study. It's very long, but it is difficult to see where it could be shortened. I have a few queries, listed below and a few corrections to spelling, grammar etc. My main concern is the very large difference between the three recruitment processes, which may mean that each has to be taken as a separate study, with inevitably small numbers. Whatever my concern, I am sure the authors can address it, and some of my comments even I think appear a bit rambling. Apologies, I have enjoyed reading the manuscript and look forward to a final version in due course. Abstract, Background, final sentence 'Paediatric low vision research' presumably means research into assistive technologies, but this is not explicit, and could be taken to refer to ALL low vision paediatric research. Suggest add extra phrase, or, if word count is tight, simply change full stop after 'such as the internet' and use semi-colon, to clarify meaning. I was surprised to find the following limitations listed: - performance and social desirability bias (masking of participants not possible) - possible differential bias between study arms (attractiveness of active intervention) The authors make it quite clear that a major benefit of a tablet is social desirability and attractiveness, and if tablets are more desirable, and therefore more likely to be used, isn't this part of what the team would like to determine quantitatively in an RCT? So how can this quality of a tablet be a limitation to the study? Page 4, Background, first sentence. I always find terms such as 'less' when describing visual acuity potentially confusing. In most scoring systems a lower value (acuity less than) means better acuity, so 'less than 6/18 could be taken to be the opposite of what is intended. If the authors use 'poorer than', it avoids any ambiguity. Please change wherever this term appears in the text. Page 4, Background, first paragraph, final sentence. This sentence is out of place here, since it reads as if it only applies to assistive technologies, whereas, of course, it applies to low-tech magnifiers as well. Can the authors rethink this? Page 6, Primary Objective, second line, 'an electronic assistive

	technologies' should be either singular or plural but this is a mixture of both Page 6, Trial design, missing 'is' in first few words Page 7, first paragraph, the authors describe what the first and third centres are (tertiary eye care facility/hospital), but not what the second, Child Development Centre in Bedford, is. Then Page 12, Recruitment seems at odds with the list of recruitment centres. Here we read that it is through the two local VI teams. Unless both have their headquarters in the Development Centre, we need some clarification. Page 8, Interventions, second paragraph. Where will the training take place? I note that 'In Bedford, a teacher for the vision-impaired will support this training.' Presumably children attending the Bedford centre will be locally based, and attending schools within the catchment area of the Bedford QTVI. Will the QTVI be offering training support in the participants' schools? Presumably in-school support for training is not feasible for participants recruited from the other two centres, since children will be attending from long distances. There is an obvious potential difference between the training and support offered and the authors should make some comment about this here. Children attending Moorfields will also have their own QTVI support in schools. Are the QTVIs of these children aware of the study and be available to the pupils for support? Is this another area of potential bias? Later, the authors suggest that the non-intervention group will have local QTVI support, as if this does not apply to the intervention group. What about the participants in India – what are the educational arrangements there and what support will the participants have that might influence device use? The above is partly answered in the next paragraph, but needs further clarification. In addition, the opening of the paragraph implies that participants receiving the intervention will NOT be offered optimal refractive correction or tints. Will they be allowed to continue to use their other LVA's if they have them, during the trial? Randomisation is mentioned but not explained until later (incidentally sometimes this is spelled with z and sometimes with s – be consistent). So at this point I was full of questions – how is randomisation to be achieved? Do pupils know in advance that they may get a tablet? How will you then handle the disappointment in the pupils not allocated to that group? All of these questions are answered eventually and I may be asking too much for the order to be changed for readers as impatient as I am. Could the authors think about ordering? One question that is not answered is: what is to stop children who own a tablet for home use, taking it to school and using it in the same way as the pupils in the intervention group? How likely is it that participants will know each other? I think this unlikely for participants recruited from Moorfields, but I imagine that children in Bedford will be quite likely to know each other through social groups etc. I am a little concerned about the three recruitment centres having such different demographics. Page 11, Ethics Approval. Explanation may not be needed for the manuscript, but I am intrigued that a study taking place in London and Bedford has approval from North Scotland! Page 12, Recruitment, line 47/48. Suggest change 'but this policy clearly states' to semi-colon 'this policy clearly states'. The use of the word 'but' implies that it is not a policy the authors approve of! Line 52/53 '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.' This sentence does not make

	sense. It is clearly the members of the VI team who will approach the young person and who are independent, not the visually impaired students! Line 57 ‘at LVPEI: a member of the clinical team will first approach patients’ add ‘and their family’ Page 13, line 11, add ‘and’ before will invite Page 14, Masking. ‘Diaries will be reviewed in masked fashion’. Apologies if I missed this, but I am not aware that diaries have been mentioned before this point.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1 Comments to Author:

I enjoyed reading the paper, it is well written and in an area that is very under-researched so it's great to see an RCT that is well designed and thought through. The collaboration between India and the UK is a definite plus and a big undertaking and the authors are to be congratulated for attempting to conduct a trial in two diverse locations.

Thank you for your kind comments on this work.

It would help to understand why the age group of 10-18 was chosen. A 10 year old is very different to an 18 year old and the 'anxieties' faced and 'educational' challenges can be very different. For example a 15-16 year old will be doing their GCSEs/10th standard exams and the educational challenges they face are very different to a 10 year old in grade 5/standard 6 student for example. How will you ensure that you get an even spread of participants across all age points.

This is a very good point and we have added some discussion to our limitation section. We used 10 as a lower age due to the assessment materials used (MNREAD, IREST). At this pilot stage, we were interested to include a wide age range, without stratification by age. In a future trial, with larger sample size, we will stratify by age.

How do you define 'educational' purposes? There really is a very fine line between what might be considered for 'leisure' and what may be considered 'educational'. For example many children play video games that have both an educational and leisure element. How does this impact your inclusion/exclusion criteria?

Agreed. We used the definition of “at school” rather than “educational” – and have emphasised that many (maybe most) children in the developed world will use tablet computers for research for homework, for example.

It isn't particularly clear from the paper that all participants will receive a standard eye exam including an up to date prescription. One group will then get a specially modified iPad and the other will get conventional low vision care. Perhaps this can be made clearer. It became obvious to me from the appendix (protocol) but not actually whilst reading the paper.

This has been clarified at the start of the “interventions” section.

What mechanisms do you have in place to ensure that participants will return iPads. Also it is not clear whether the iPads will be wifi/3G enabled, which would increase what they can potentially be used for.

We will rely on the goodwill of parents or carers to return the device and they will be appropriately security marked. The iPads used in the UK will be wi-fi only devices and will use schools' own wi-fi networks. For India, the iPads will additionally have mobile data (3G) connections.
This has been added to the manuscript.

Please clarify.
How will you ensure that the diaries are filled in accurately? Please clarify.

We will encourage children and their parents/carers to help fill in the diary but have no means of checking their accuracy. We have added this limitation to the discussion.

This is more of an ethical question (although I note you already have ethical approval and this therefore is a mute point), but what would you do if the child did not want to return the iPad because they loved it so much?

Some of the schools our participants attend now provide tablet computers to the children, based on the positive experience. Children are altruistic and understand the concept of sharing, meaning that they have to return them so that other children can "have a go".

There are some differences between the paper and the protocol in the appendix. For example the AME (Sight App) is mentioned in the protocol but the ViaOptaDaily app is mentioned in the paper. The protocol mentions MNREAD, there is no mention in the paper. Could you clarify why this is the case?

The AME software was not used in the final study as the version available at recruitment was not sufficiently stable.
MNREAD analysis is performed at each visit and was accidentally missed out from the paper. It has been included.

Would it be worthwhile adding that statistical data analysis will be carried out by CB (not involved in any way with actual data collection etc.)- this is clear in the protocol but not in the paper

This has been clarified (it will actually be AQ)

Is 6/18 not 0.50LogMAR not 0.48LogMAR?

It's often rounded to this but log10(6/18)=0.477. 0.5 logMAR is actually 6/18.97.

Page 6 line 5 says that the cost of CCTVs hasn't changed in 20 years, the protocol says 10 years. Be consistent.
Thank you – changed to "remained high".

Reviewer: 2
Reviewer Name: J M Woodhouse
Institution and Country: Cardiff University, UK
Please state any competing interests: None declared

Please leave your comments for the authors below

This is comprehensive and well-written description of a pilot study. It's very long, but it is difficult to see where it could be shortened. I have a few queries, listed below and a few corrections to spelling, grammar etc. My main concern is the very large difference between the three recruitment processes, which may mean that each has to be taken as a separate study, with inevitably small numbers. Whatever my concern, I am sure the authors can address it, and some of my comments even I think appear a bit rambling. Apologies, I have enjoyed reading the manuscript and look forward to a final version in due course.

Thank you!

Abstract, Background, final sentence 'Paediatric low vision research' presumably means research into assistive technologies, but this is not explicit, and could be taken to refer to ALL low vision paediatric research. Suggest add extra phrase, or, if word count is tight, simply change full stop after 'such as the internet' and use semi-colon, to clarify meaning.

Good point: changed to: Research on these devices in low vision has been limited to case series.

I was surprised to find the following limitations listed:
- performance and social desirability bias (masking of participants not possible)
- possible differential bias between study arms (attractiveness of active intervention)
The authors make it quite clear that a major benefit of a tablet is social desirability and attractiveness, and if tablets are more desirable, and therefore more likely to be used, isn't this part of what the team would like to determine quantitatively in an RCT? So how can this quality of a tablet be a limitation to the study?

True. We mean that drop-outs may be less frequent in the group with the tablets, which may affect the power of our study. We have added this to clarify: 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.

Page 4, Background, first sentence. I always find terms such as 'less' when describing visual acuity potentially confusing. In most scoring systems a lower value (acuity less than) means better acuity, so 'less than 6/18 could be taken to be the opposite of what is intended. If the authors use 'poorer than', it avoids any ambiguity. Please change wherever this term appears in the text.

Agreed, and changed.

Page 4, Background, first paragraph, final sentence. This sentence is out of place here, since it reads as if it only applies to assistive technologies, whereas, of course, it applies to low-tech magnifiers as well. Can the authors rethink this?

We have restructured the paragraph to read:

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.

Page 6, Primary Objective, second line, 'an electronic assistive technologies' should be either singular or plural but this is a mixture of both

Corrected

Page 6, Trial design, missing ‘is’ in first few words

Corrected

Page 7, first paragraph, the authors describe what the first and third centres are (tertiary eye care facility/hospital), but not what the second, Child Development Centre in Bedford, is.
Thank you – we have added “a multidisciplinary community health, education and social care facility for children with developmental needs and disabilities”.

Then Page 12, Recruitment seems at odds with the list of recruitment centres. Here we read that it is through the two local VI teams. Unless both have their headquarters in the Development Centre, we need some clarification.

Thank you – we have changed this to “CDC: Students known to the Bedfordshire teachers for visually impaired students will be approached, along with their family”

Page 8, Interventions, second paragraph. Where will the training take place? I note that ‘In Bedford, a teacher for the vision-impaired will support this training.’ Presumably children attending the Bedford centre will be locally based, and attending schools within the catchment area of the Bedford QTVI. Will the QTVI be offering training support in the participants’ schools? Presumably in-school support for training is not feasible for participants recruited from the other two centres, since children will be attending from long distances. There is an obvious potential difference between the training and support offered and the authors should make some comment about this here. Children attending Moorfields will also have their own QTVI support in schools. Are the QTVIs of these children aware of the study and be available to the pupils for support? Is this another area of potential bias?

Yes, the QTVIs are informed of children’s involvement in the study, and letters are sent to the QTVI, SENCo and class teacher as appropriate asking for the young person to be allowed to use their device in school. This has been clarified.

Later, the authors suggest that the non-intervention group will have local QTVI support, as if this does not apply to the intervention group.

Both groups have QTVI support – this has been clarified.

What about the participants in India – what are the educational arrangements there and what support will the participants have that might influence device use?

Although we have teachers for visually impaired (TVI) in India, they are typically employed in special schools for the blind and are well versed with Braille. We do not have such a support system for children with low vision in schools. However, most teachers of these schools encourage children to use the prescribed low vision devices and make the required arrangements in the classroom, for example, seating in first row and providing extra time to copy from the board. Similar to that in the developed world, children with low vision in our study (South India) were provided 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 above is partly answered in the next paragraph, but needs further clarification. In addition, the opening of the paragraph implies that participants receiving the intervention will NOT be offered optimal refractive correction or tints. Will they be allowed to continue to use their other LVA’s if they have them, during the trial?

Yes, this is clarified in the manuscript.

Randomisation is mentioned but not explained until later (incidentally sometimes this is spelled with z and sometimes with s – be consistent). So at this point I was full of questions – how is randomisation to be achieved? Do pupils know in advance that they may get a tablet? How will you then handle the disappointment in the pupils not allocated to that group? All of these questions are answered eventually and I may be asking too much for the order to be changed for readers as impatient as I am. Could the authors think about ordering?

On a practical level, we address this as “You will receive an iPad, either today or in six months”.

One question that is not answered is: what is to stop children who own a tablet for home use, taking it to school and using it in the same way as the pupils in the intervention group?

This is a problem – as is children being given a tablet by the local VI team during the 6 months of data collection. This will lead to exclusion from the study. We have clarified this in the manuscript:
Should participants in the control group receive a tablet computer from their local visual impairment team, 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.

How likely is it that participants will know each other? I think this unlikely for participants recruited from Moorfields, but I imagine that children in Bedford will be quite likely to know each other through social groups etc. I am a little concerned about the three recruitment centres having such different demographics.

This is a deliberate attempt to explore differences in recruitment, practicality, and benefit of devices in three very diverse settings.

Page 11, Ethics Approval. Explanation may not be needed for the manuscript, but I am intrigued that a study taking place in London and Bedford has approval from North Scotland!

When submitting the IRAS form, we opted for the REC with the next available meeting to discuss our proposal, and that happened to be in Scotland.

Page 12, Recruitment, line 47/48. Suggest change ‘but this policy clearly states’ to semi-colon ‘this policy clearly states’. The use of the word ‘but’ implies that it is not a policy the authors approve of!

This is unintentional! We have removed “but”.

Line 52/53 ‘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.’ This sentence does not make sense. It is clearly the members of the VI team who will approach the young person and who are independent, not the visually impaired students!

Corrected

Line 57 ‘at LVPEI: a member of the clinical team will first approach patients’ add ‘and their family’

Corrected

Page 13, line 11, add ‘and’ before will invite

Corrected

Page 14, Masking. ‘Diaries will be reviewed in masked fashion’.

Apologies if I missed this, but I am not aware that diaries have been mentioned before this point.

This is under “primary outcomes” – we have added more paragraph breaks which should make it easier to identify the different outcomes used.

VERSION 2 – REVIEW

REVIEWER	Ahalya Subramanian City, University of London United Kingdom
REVIEW RETURNED	03-Apr-2017

GENERAL COMMENTS	The authors have adequately addressed all my comments and I don't have further comments to add.