
The Experience of a Randomized Clinical Trial of Closed-Circuit Television Versus Eccentric Viewing Training for People with Age-Related Macular Degeneration

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Structured abstract: *Introduction:* In addition to optical devices, closed-circuit televisions (CCTVs) and eccentric viewing training are both recognized interventions to improve reading performance in individuals with vision loss secondary to age-related macular degeneration. Both are relatively expensive, however, either in the cost of the device or in the amount of time personnel need to provide training. In this randomized trial, we compared the effectiveness of these two interventions. *Methods:* Participants with age-related macular degeneration and visual acuity between 6/48 (20/160) and 6/120 (20/400) first received basic low vision care, including optical devices. At the subsequent baseline visit, they undertook a battery of measures including logMAR visual acuity; reading speed and accuracy for text in 1.3M and 1M fonts; reading information on medicine bottles, utility bills, and food packages; the NEI-VFQ; the Geriatric Depression Scale; and a reading inventory questionnaire. They were then randomized to either obtaining a CCTV for home use or eccentric viewing training over the following six weeks. *Results:* Recruitment was more difficult than expected for this population. Of 145 patients referred, 29 met the inclusion-exclusion criteria, 14 were willing to enroll, and 10 completed the trial. For the primary outcome (reading speed for 1.3M print), there was a significant improvement between baseline and outcome for the CCTV group ($p = 0.005$), but not for the eccentric viewing training group ($p = 0.28$), and the CCTV group showed significantly greater change ($p = 0.04$). There was a nonsignificant improvement in reading speed for 1M text and a decrease in the amount of time taken to read utility bill information in the CCTV group. There was a significant improvement in near visual acuity with current glasses with eccentric viewing training. The other measures did not reach statistical significance. *Discussion:* Randomized clinical trials for low vision rehabilitation, particularly in the elderly population with vision loss, are challenging, but such trials are important for the allocation of resources. This trial showed early indications of more impact on reading performance from CCTV than eccentric viewing training.

In Western countries, age-related macular degeneration is the most frequent cause of severe visual impairment (Klein, Lee, Gangnon, & Klein, 2013; Quartilho et al., 2016) and reading is the most common goal—it is the first or second rehabilitation goal for 96% of this population (Elliott et al., 1997). People with age-related macular degeneration usually require magnification in order to be able to read standard print. Magnification can be provided either by optical devices or, for moderate and advanced vision loss, electronic video enhancement systems or video magnifiers, commonly called closed-circuit televisions (CCTVs). The significant advantages of CCTV over optical magnifiers are that it provides high levels of magnification with a greater field of view (compared to the equivalent optical device); allows reading at a more typical viewing distance of about 40–50 cm (15.8”–19.7”); and allows binocular viewing (which higher-powered optical magnifiers cannot) (Peterson, Wolffsohn, Rubinstein, & Lowe, 2003). There is a general consensus among studies that reading speeds are faster with CCTVs compared to optical magnifiers and that the duration of reading is increased

(Goodrich & Kirby, 2001; Peterson et al., 2003).

Those with more advanced age-related macular degeneration develop a central scotoma, which necessitates the development of a preferred retinal locus for fixation, instead of the dysfunctional anatomical fovea. Although preferred retinal locus development occurs naturally with time for the majority of patients (Crossland, Culham, Kabanarou, & Rubin, 2005; Fletcher & Schuchard, 1997), it is thought that in many cases the naturally developed preferred retinal locus is not in the ideal position (Fine & Rubin, 1999; Fletcher & Schuchard, 1997; Nilsson, 1990; Petre, Hazel, Fine, & Rubin, 2000). Therefore, eccentric viewing training is commonly recommended (Owsley, McGwin, Lee, Wasserman, & Searcey, 2009; Stelmack, Massof, & Stelmack, 2004) with several purposes in mind: to develop the more consistent and efficient use of a preferred retinal locus; to speed up the process of developing a preferred retinal locus; and to optimize the preferred retinal locus position (Gaffney, Margrain, Bunce, & Binns, 2014).

Both of these interventions for more advanced vision loss are relatively expensive. Currently, handheld and tabletop CCTVs range in price from \$500 to \$3,000. The amount of time involved in eccentric viewing training varies between approximately 1 and 14 hours (Gaffney et al., 2014; Stelmack et al., 2004), with an estimated average of 4 hours (Stelmack et al., 2004), and it is costly if undertaken by an occupational therapist or low vision therapist, since their fees for 4 or up to 14 hours of work needs to be paid by the government, private insurance, or the patients themselves. Interestingly, we do

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not know the dose effect for eccentric viewing training—that is, it is not known how much is sufficient to gain the near maximum improvement and at what point further training does not yield further benefit (Gaffney et al., 2014). There are very few randomized clinical trials of the effectiveness of eccentric viewing training, and even fewer in comparison to other interventions (Gaffney et al., 2014; Hamade, Hodge, Rakibuz-Zaman, & Malvankar-Mehta, 2016).

Depending on what is funded or affordable for patients, some clinics may spend more resources on eccentric viewing training while others spend more on electronic devices. In the province of Ontario, Canada, there may be a tendency to use resources for CCTVs, since these are funded through the Assistive Devices Program (ADP) for eligible individuals (Ontario Ministry of Health and Long Term Care, 2008).

In an ideal world, one might want to include both CCTV and eccentric viewing training, but given the reality of limited resources, agencies need to consider which of these treatments or interventions would have the bigger impact. Assuming that resources are not limitless, it is important to know which interventions are more effective in order to improve reading for people with age-related macular degeneration. To answer this question, we initiated a randomized clinical trial of CCTV provision versus eccentric viewing training for people with moderate to advanced age-related macular degeneration who had already received a low vision assessment and appropriate optical devices. The primary hypothesis was that a CCTV would provide greater increases in reading speed compared to eccentric view-

ing training (specifically, that it would improve reading speed by at least 10 words per minute for 1.3M print). Secondary outcomes were: reading accuracy for 1.3M reading speed, and accuracy for 1M print, and reading performance for utility and telephone bills and a medicine bottle label. The following instruments (questionnaires) were also used to measure outcomes: a reading behavior inventory, the VFQ-25 plus questions 3 and A4, and the Geriatric Depression Scale.

Methods

This study was a prospective, randomized, parallel-armed clinical trial. The setting was CNIB (formerly Canadian National Institute for the Blind), Toronto, Canada, which draws patients from a broad population base of six million in the Greater Toronto area in southern Ontario. We aimed for an initial sample of 30 participants. Inclusion and exclusion criteria are listed in Table 1. The better end of the visual acuity range was selected so that prospective participants would have been likely to have central vision loss and require CCTV or eccentric viewing training, and the poorer limit was chosen because individuals with poorer vision than the range specified would have been unlikely to benefit sufficiently from the optical devices that would be provided to those in the eccentric viewing training group of the study.

The study received ethics clearance through the Western University Research Ethics Board and followed the tenets of the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects. All participants gave written informed consent. This

Table 1
Inclusion and exclusion criteria.

Initial inclusion criteria	Relaxed inclusion criteria
Diagnosis of AMD reducing visual acuity to between 20/160 and 20/400 (logMAR 0.9–1.3) in the better eye	For referral to the study, the lower limit of VA was changed to 20/630, so as to allow for the possibility of improvement with new glasses
First-time patient at CNIB	Unchanged
Aged over 50 years	Unchanged
No previous EVT or CCTV	Unchanged
Able to read English	Unchanged
A helper at home to help with EVT	Unchanged
Exclusion criteria	Relaxed exclusion criteria
No anticipated ocular treatment including anti-VEGF treatment over the course of the study	No anticipated ocular treatment except for anti-VEGF treatment over the course of the study
Reading not being a goal	Unchanged
Minimental (Folstein, et al., 1975) score < 22 (the copy design task was enlarged to a 8.5 × 11 page)	Unchanged
Other ocular disease reducing central vision	Unchanged

AMD = age-related macular degeneration; EVT = eccentric viewing training; CCTV = closed-circuit television.

clinical trial was registered with Clinical-Trials.gov (2017).

The study protocol is shown in Figure 1. After patients had received a standard low vision assessment from the low vision therapist at CNIB and met the initial eligibility criteria (diagnosis, reading as a goal, English language ability, and no obvious cognitive difficulties), they were invited to participate. The low vision assessment included: case history and goal assessment; distance visual acuity with the Early Treatment Diabetic Retinopathy Study (ETDRS) chart; near visual acuity with continuous text print; contrast sensitivity assessment; determination of magnification; a trial of optical devices; and modification of magnification to determine the optimum device and magnification. The magnification was based on the near reading acuity and the goal print size (which was 1.3M or the patient's own

goal, whichever was smaller), and incorporating a 2X acuity reserve (Lovie-Kitchin, 2011). The final device was the one that gave maximum reading fluency for the target print size. Demonstration of reading stands, line guides, illumination, and fit-overs for glare was also included. If the optimum aid for reading was a handheld or stand magnifier, this device was provided through the CNIB. The client was directed to go to his or her eye care practitioner for provision of spectacle-mounted microscopes (prism half eye or full field microscope). Fit-overs for glare were available through CNIB, and prescription tints were provided through the eye care practitioner. To increase recruitment, we asked optometrists in Toronto who were known to offer low vision services to refer potential participants. In these cases, the initial low vision assessment and provision of

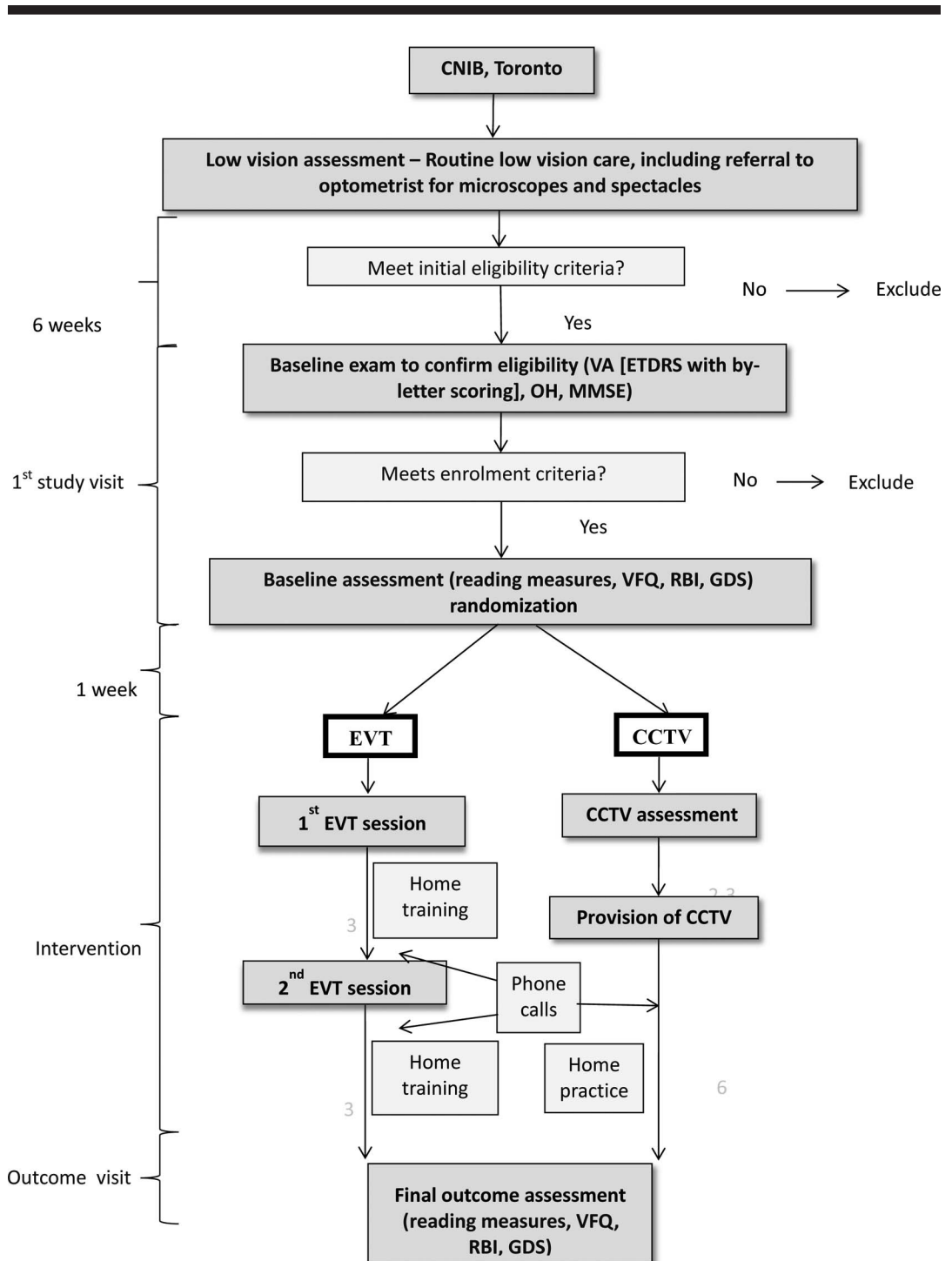


Figure 1. Study protocol. VA = visual acuity; OH = ocular health; MMSE = Mini Mental Status Exam; VFQ = VFQ-25; RBI = Reading Behavior Inventory; GDS = Geriatric Depression Scale; EVT = eccentric viewing training; CCTV = closed-circuit television.

optical devices were undertaken by the optometrist.

BASELINE VISIT

After a six-week period to allow participants time to visit their eye care practitioners, obtain microscopes, and practice with standard low vision devices, the participants attended CNIB for the baseline assessment. An eye care practitioner performed an eye examination to determine eligibility regarding the eye condition or conditions and ocular history. Then the following were performed and recorded: ETDRS distance visual acuity for both eyes with by-letter scoring, near reading acuity with the current spectacles for both eyes with the Lighthouse chart, reading acuity with the current optical aid, the type of optical aids, Mini Mental Status Exam (MMSE), Geriatric Depression Scale, and a check for fulfillment of other inclusion criteria.

Reading speed and accuracy were assessed with elementary school fifth grade-level texts that were approximately 150 words long in either 1.3M or 1M print. Print that is 1.3M is equivalent to 12-point font, which is commonly used in letters and documents, whereas 1M print represents average newsprint. Four passages were selected that had been previously validated in the lab of Dr. Leat. The paragraphs did not contain uncommon proper nouns or any quoted speech. Out of eight candidate paragraphs, four paragraphs were selected and matched in pairs to the closest Flesch-Kincaid grade and the closest (almost identical) average reading speeds. Two were assigned to the 1.3M print and two to the 1M print. The order of the two paragraphs for each print size was

randomized to baseline or outcome between participants. For this task, participants were allowed to use their preferred optical devices and were allowed to adjust the lighting (both were recorded). They were asked to read out loud as fast as possible, but without sacrificing accuracy. After a demonstration of the task with a different text, participants were asked to read the paragraphs. The participant was handed the text, and timing with a stopwatch started when reading began. All errors were recorded. The number of correct words per minute and the number of errors per 100 words were calculated.

Three other reading tasks were included, which were modeled on Dougherty et al. (2009). These were: reading the amount due on a utility bill, microwave cooking time that was indicated on a food package, and the patient's name and dosage (number of tablets per day) on a medicine bottle. The amount of time taken and the accuracy were recorded for each. As for the text reading, participants were allowed to use their preferred devices and lighting. They chose their preferred lighting and device using a demonstration version of each task. There were two versions of each task, which were randomized between participants to baseline or outcome visit. There was an upper time limit of two minutes for each of these tasks, after which time they were recorded as incorrect if the patient had not responded.

Participants were asked verbally about their reading patterns using Questions 1 and 3 from the Reading Behavior Inventory (Goodrich, Kirby, Wood, & Peters, 2006). The NEI-VFQ25 (Mangione et al.,

CCTV intervention

The 22" Clearview tabletop CCTV was used for all participants in the study.

CCTV assessment (within one week of randomization). This was based on the standard Assistive Devices Program (ADP) assessment procedure, briefly described as follows:

After determining the participant's reading goals, the minimum magnification to read the goal print was assessed, the magnification was recorded, this magnification was multiplied by 5X, and then the participant was allowed to increase or decrease magnification until they could comfortably and fluently read the goal print. This magnification was recorded and the preferred polarity was determined. Last, the participant was trained to use the CCTV controls.

The CCTV was delivered and set up at the patient's house.

The participant was asked to use the CCTV for a minimum of two sessions of 10 minutes each day during a six-week period.

During the trial period, the participant received two phone calls with standard questions to check the setup and their use of the CCTV.

CCTV = closed-circuit television.

Box 1

2001) was administered using standard procedure, with the additional instruction "if you use a low vision device for an activity, please answer the questions as though you were using it." The additional questions A3 and A4 were included, giving a total of 27 questions. Last, the Geriatric Depression Scale-15 was administered (Yesavage et al., 1982).

After these tasks, participants were randomized into either the CCTV or the eccentric viewing training group. Randomization was stratified by presenting visual acuity (group 1: 0.90–1.00 logMAR; group 2: 1.00–1.20; group 3: 1.20–1.3). The intervention protocols are shown in Boxes 1 and 2. The duration of both interventions was six weeks. The eccentric viewing training was undertaken by a low vision therapist and the protocol included components which are commonly included by low vision therapists (Stelmack et al., 2004).

OUTCOME VISIT

The outcome assessment was the same as the baseline, with the exception that participants in the CCTV group were asked to use the CCTV for the reading texts and those in the eccentric viewing training group were asked to use their trained preferred retinal locus. For the other reading tasks (the utility bill, medicine bottle, and food package), participants were allowed to use whichever device, viewing strategies, and lighting that they preferred—that is, those in the CCTV group could choose to use their optical device or the CCTV. After the outcome visit, both groups were offered the alternative treatment.

DATA ANALYSIS

The reading speed measurements were calculated in \log_{10} correct words per minute (\log CWMP) for analysis. The main

Eccentric viewing training intervention

First EVT training visit (within one week of randomization, duration 1.5 to 2 hours)

- For the better eye, the central scotoma was plotted with a tangent screen.
- Training started with blind-spot awareness (Fletcher & Schuchard, 1997) using the face method.
- The likely direction of eccentric viewing was determined from the tangent screen plot, confirmed with the clock or face method. If the field loss was symmetric around fixation, the participant was asked to move their gaze upwards (since this is one of the most common and effective directions for EVT (Fletcher & Schuchard, 1997; Petre et al. 2000). If there was an asymmetric scotoma, the participant was asked to move their gaze to give the best horizontal area of intact visual field for reading, extending to the right, and which was nearest to fovea. This gaze shift was demonstrated with the Amsler chart or tangent screen.
- The direction was confirmed with the clock or face method. The participant was asked to fixate on the center of the trainer's face or a clock and to note which section of the face or numbers on the clock were clearest. Fixation was moved away from the clearest section. If there was no clear preference, the EVT position would be chosen to be upwards (as above).
- Using Quillman-type exercises, a print size two times larger than the participant's near visual acuity (with their bifocal glasses) was chosen. The participant was trained to move their fixation in the direction of the determined EVT. The amount of improvement in near visual acuity for print with EVT was determined.
- Quillman-type exercises in a range of print sizes were provided (including threshold and 2X smaller and 2X larger than threshold) for both with and without the optical magnifier.
- Last, the EVT was demonstrated with the participant's own optical aid.
- For the home training, the participant was asked to practice with an observer and simply give feedback regarding their level of accuracy.
- They were asked to practice for at least two sessions of 10 minutes each per day for three weeks.

The participant received one phone call with standard questions between sessions 1 and 2 to check their compliance and use of an observer.

Second EVT visit (three weeks later, duration 1.5 to 2 hours)

- After reviewing the participant's progress, steady-eye strategy (Gaffney et al., 2014) was demonstrated, during which the participant maintains his or her fixation in the EVT position, rather than making a fixation movement to each word and then to the EVT position.
- A new range of exercise print sizes was determined and provided. The participant was asked to practice for another three weeks.

EVT = eccentric viewing training; CCTV = closed-circuit television.

outcomes, which are the reading speeds and accuracies, were analyzed by two-way two-sample *t*-tests between the pre- and post-results for the CCTV and eccentric viewing training groups. Paired *t*-tests were also undertaken between the pre- and post-measures for each group separately.

Results

In this study, we aimed for 30 participants. After 8 months, only 3 had been recruited, and only 7 by 1 year. We lost potential participants at each step of the recruitment process. At the end of 2 years, of 145 patients referred to CNIB in that time frame, 35 charts were reviewed as potential participants, 29 met the inclusion-exclusion criteria (the others either did not meet the visual acuity requirement, had communication difficulties secondary to English as a second language, or had a lack of support to perform the eccentric viewing training at home). Of these 29, 14 were willing to participate (the others were not willing for reasons including unwell health, feeling there would be travel difficulties (despite being offered a taxi service), having too many doctor's appointments, feeling that they could not ask their child to take them to more appointments, believing that they would not benefit, lacking the patience to do daily training, or being uninterested. At the next visit (the baseline visit), we also lost participants whose visual acuity was improved to better than the inclusion criterion after they received new spectacles from their eye care practitioner whom they had seen between visits. Early in the recruitment process, we realized that the inclusion criteria were too strict (although

ideal). We relaxed them as indicated in Table 1.

After 18 months, to recruit more participants, a decision was made to move the study to CNIB, London, Ontario, another large city where CNIB is the largest provider of low vision services. Eventually, after 2 years of recruitment, a decision was made to close the study.

Of the 10 participants who finally completed the study, 4 were randomized to the eccentric viewing training group (average age 82, 2 of whom were female) and 6 to the CCTV (average age 83.5, 3 of whom were female).

At baseline, there were no significant differences in distance visual acuity, reading speeds, reading accuracy, the amount of time taken for reading tasks, MMSE, Geriatric Depression Scale, or the VFQ (composite score or any subscales) between the two groups ($p > 0.05$). However, there was a significant difference in near logMAR visual acuity with the current glasses (eccentric viewing training group = 1.42, CCTV group = 1.3, $p = 0.035$), where a higher logMAR score represents poorer visual acuity.

Figure 2 shows the primary outcome variable (reading speed for 1.3M text). Within the CCTV group, there was a significant improvement at the outcome visit compared to the baseline (paired *t*-test, $p = 0.005$), but not within the eccentric viewing training group ($p = 0.28$). A two-sample *t*-test of the changes (pre-post) showed a significant difference between the groups ($p = 0.04$). Figure 3 shows the secondary outcome of reading speed for 1M text. There was no significant change in the reading speed

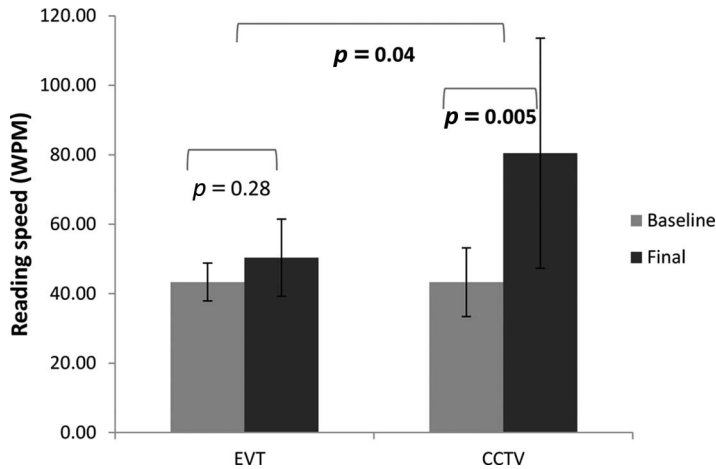


Figure 2. Primary outcome: Reading speed for 1.3M text (average \pm SD).

within the eccentric viewing training or the CCTV group, although this almost reached significance within the CCTV group ($p = 0.051$). The between-groups difference in change (pre-post) did not quite reach significance ($p = 0.089$). Similar analyses for accuracy showed no significant differences.

Figure 4 shows the results for the amount of time taken to read the utility bill. There was, however, a significant improvement in the amount of time taken within the CCTV group, but not

within the eccentric viewing training group, and there was no significant difference in the change (pre-post) between the groups. It is noteworthy that the large variability in the amount of time taken at baseline is mostly due to one individual who read the bill very quickly.

Figure 5 shows the changes in near visual acuity. There was a significant improvement in near visual acuity (with current eyeglasses) within the eccentric viewing training group, but no signifi-

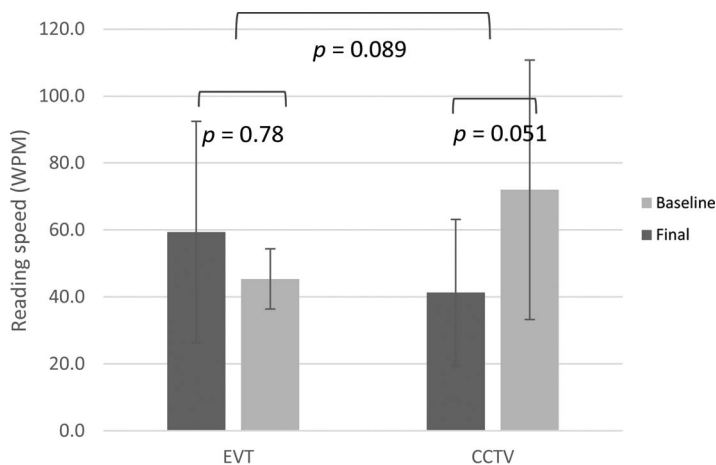


Figure 3. Secondary outcome: Reading speed for 1M text (average \pm SD).

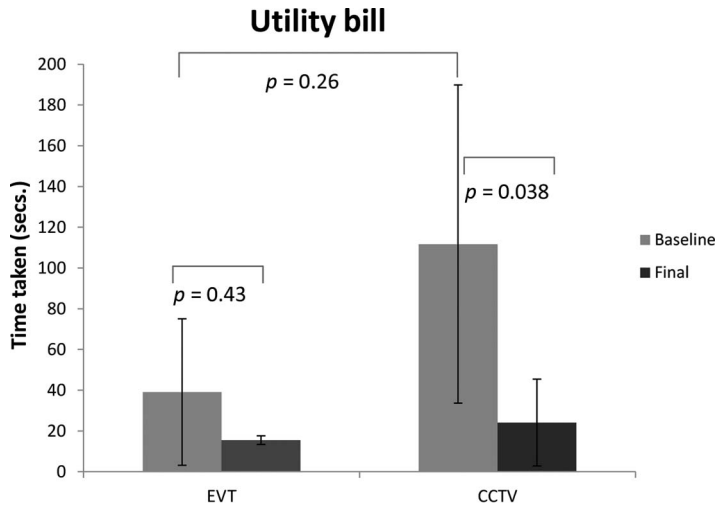


Figure 4. Amount of time taken to read the utility bill (average \pm SD).

cant difference pre-post between the groups.

For all other measures there were no significant differences between or within the groups.

Discussion

Despite the small sample size, this trial showed early indications of more improvement in reading speed with CCTV than from eccentric viewing training. There was a significant improvement in

the main outcome variable (reading speed for 1.3M print) in the CCTV group and between the two groups. There was no significant improvement in reading speed within either group for 1M print, although it almost reached significance within the CCTV group. There was faster performance with the utility bill within the CCTV group. These results are in agreement with the results of Vukicevic and Fitzmaurice (2005), in which they found that eccentric viewing training did

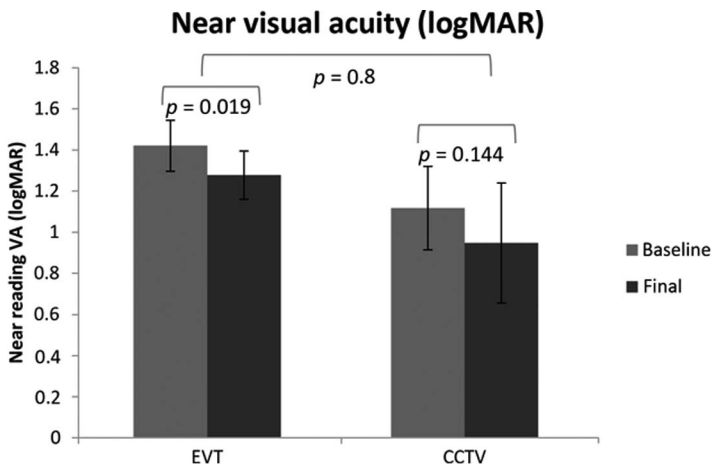


Figure 5. Near reading acuity with own eyeglasses (average \pm SD).

not make any further improvement over magnification in the performance of daily living tasks that require high acuity, while eccentric viewing training either with or without magnification improved participants' perceived ability for low-acuity tasks such as shopping or household chores. Studies of eccentric viewing training alone have shown a modest increase of reading speed of 25% to 34% (Kasten, Haschke, Meinhold, & Oertel-Verweyen, 2010; Verdina et al., 2013). We found an increase of 16% with eccentric viewing training with 1.3M print (which was not significant) compared to an 86% increase with CCTV for 1.3M and 74% for 1M print. These increases with CCTV are similar to those found by Peterson et al. (2003), who reported that reading with a stand-mounted CCTV was 73% faster than with an optical aid. This finding indicates that for the task of reading, CCTV will give the greater benefit.

Interestingly, in the present study, near visual acuity with the participants' own spectacles improved after eccentric viewing training. This latter finding may indicate that eccentric viewing training has a place in the armory of low vision rehabilitation interventions. Although visual acuity was still reduced (logMAR 1.28, which is close to 20/400), some improvement may be obtained for low-acuity tasks such as dressing, grooming, and mobility (Vukicevic & Fitzmaurice, 2005). But for high-acuity, reading-related tasks, magnification is still required, since even with eccentric viewing training visual acuity is limited by the use of the preferred retinal locus, which is eccentric to the fovea—that is, eccentric viewing training must be in combination with

either optical or electronic magnifying devices.

This study illustrates how undertaking randomized clinical trials—particularly those for elderly people with vision loss—is challenging, which may be part of the reason that there are very few randomized clinical trials of low vision rehabilitation (Leat, 2016). Many of those that do exist compare usual rehabilitation with a delayed provision of services (Stelmack et al., 2008; Stelmack, Tang, Wei, & Massof, 2012). Reeves, Harper, and Russell (2004) recruited 194 participants for a study comparing conventional low vision rehabilitation with low vision rehabilitation that was “enhanced” with home visits. There are also very few randomized clinical trials of eccentric viewing training (Gaffney et al., 2014). Vukicevic and Fitzmaurice (2005) compared eccentric viewing training, eccentric viewing training plus magnification, magnification alone, and a nonintervention group. However, they combined a previous pilot eccentric viewing training group with the randomized eccentric viewing training group, and it also appears that the eccentric viewing training was done with a computer program at home.

To undertake this type of trial, a large, accessible population or multicenter trials are required to recruit a sufficient number of participants, since there are many reasons why people are ineligible or are not able or willing to participate. In particular, it may be difficult to recruit visually impaired participants to studies that involve multiple visits and training. Although eccentric viewing training is undertaken at CNIB, it does not usually require the person to return for multiple visits. When part of the study involves an

effortful training program, participants who are already elderly and visually impaired, and who are often experiencing multiple morbidities, may be reluctant to take part.

We originally set up the inclusion-exclusion criteria to be optimal for a successful outcome, but had to relax a number of these (see Table 1). For example, it was ideal that no ocular treatment of any kind should be undertaken during the trial, since this might have changed visual function and have influenced the results. But we had to change this criterion in the case of anti-VEGF treatment, since it is so common in the relevant population. However, the strength of a randomized clinical trial such as the present study is that the randomization between groups ensures that this factor would be similar between the groups at the close of the study.

Randomized clinical trials are considered the strongest form of study for a clinical intervention, but it is clear that they are difficult and not possible in all situations. Nor is it possible to always mask the personnel who perform the outcome assessment as to which group a participant belongs. For example, in the current study it was clear whether the participant was using a CCTV or not. Despite the difficulties of these types of trials in this population, more are needed in order to obtain a larger evidence base for optimum and cost-efficient provision of low vision rehabilitation.

Conclusion

Randomized clinical trials for low vision rehabilitation, particularly in the elderly population, are challenging, but such trials are important for allocation of resources. This randomized clinical trial did

show early indications of more impact on reading speed from CCTV than from eccentric viewing training. In most situations where funds are limited, it seems that providing CCTV would be more effective for people's primary goal than would eccentric viewing training.

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