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### **Contribution to evidence in low-vision rehabilitation: Effects of CCTV training in visually impaired patients**

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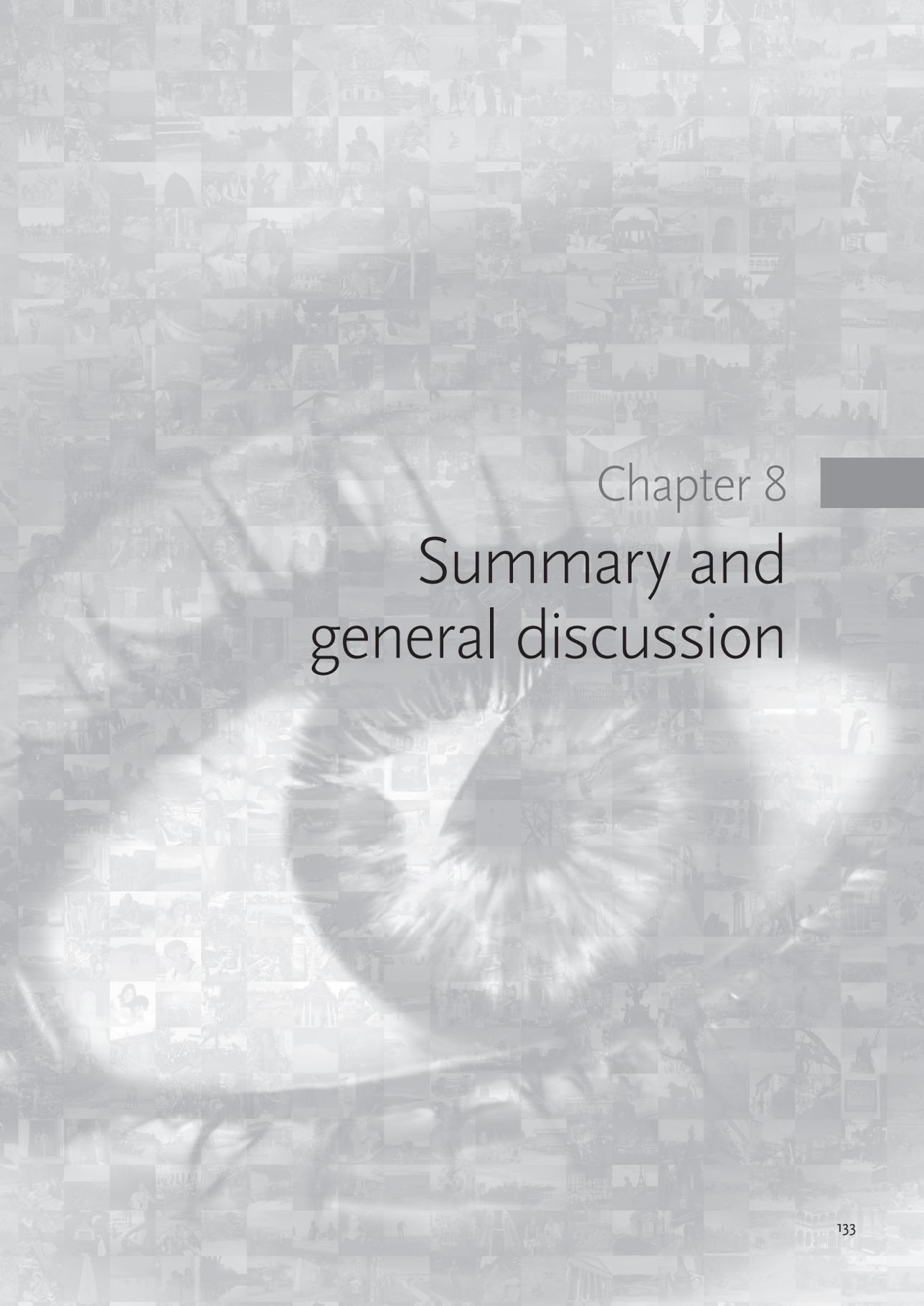
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Chapter 8

# Summary and general discussion

## Introduction

For a person with low-vision, reading has been identified as one of the most important goals to achieve.<sup>1-3</sup> Generally speaking, the size of everyday print is too small to be read comfortably at a 'normal' distance.<sup>4</sup> Reading problems can be addressed by prescribing low-vision devices (LVAs). For example, a closed-circuit television (CCTV) is an electronic vision-enhancement device which offers direct access to all kinds of printed materials by offering high amounts of magnification.<sup>4,5</sup> In fact, CCTVs offer a higher magnification than most optical magnification aids and also have many other advantages, including: contrast enhancement, image manipulation, reduction of aberrations, less critical focus, improved natural working distances, better posture, binocularity, and a longer duration of reading.<sup>6-8</sup> On the other hand, CCTVs are expensive, most types are not portable, and it requires some effort to learn how to use a CCTV effectively. To overcome the latter problem most rehabilitation centers offer training in the use of this aid. Although studies have shown that training is beneficial,<sup>4,6,9-18</sup> it remained unclear whether the improvement in reading ability can be attributed to the training provided by the low-vision therapists, or to the patients practicing on their own.<sup>12</sup> Studies addressing this question showed considerable variation in type and extent of training and often used a within-patient design, whereas a randomized controlled trial (RCT) is considered to provide a higher quality of evidence.<sup>19</sup> To our knowledge only two RCTs have been conducted, and they were inconclusive as to whether training and/or familiarity with CCTVs had contributed to improvement in reading performance.<sup>16;20</sup> Also, because one of these studies concentrated on a small number of young subjects<sup>16</sup> and in the other only a two-minute training program was offered,<sup>20</sup> the results of these studies have low generalizability. Furthermore, most studies on CCTV performance concentrated on objective outcome measures such as reading speed, whereas quality of life and task performance in daily living from the patient's perspective are also important outcome measures.

Therefore, the aim of the work presented in this thesis was to estimate the effectiveness of a structured training protocol in the use of CCTVs on different outcome measures, in an RCT among low-vision patients in the Netherlands. The development of the training program, the design and methodology of the trial, and the treatment effects on reading performance, quality of life, task performance and rehabilitation goal achievement in daily living are presented in *Chapters 4 to 7* (the main chapters), whereas *Chapters 2 and 3* (the preceding chapters) describe the prescription of low-vision aids by two types of rehabilitation services in the Netherlands and the validation of a reading test used to obtain information on the primary outcome measure, i.e. reading performance.

## Preceding chapters

This section presents a summary and discussion of the prescription of low-vision aids to visually impaired patients referred to monodisciplinary (optometric) or multidisciplinary rehabilitation services. Furthermore, the feasibility of an existing reading chart was tested in low-vision patients to obtain a reliable instrument to measure reading speed in low-vision patients, with and without their low-vision aids (LVAs).

### Optometric and multidisciplinary approaches in prescribing LVAs

#### Background

most earlier studies focused mainly on comparative reading performance with CCTVs and less costly optical aids, to determine the effectiveness of both types of LVAs and their place in low-vision services.<sup>6;14;17</sup> In a study by Goodrich et al.,<sup>13</sup> the benefit of a CCTV appeared to be in excess of 160% greater productivity compared to the prescribed optical aid, and was perceived as the 'aid of choice' in patients with central field loss. In a review by Virgili and Acosta it appeared that stand-mounted CCTVs were preferred to optical aids (i.e., with respect to reading speed), but the difference was of borderline significance; the authors concluded that there was no evidence to support the use of a specific type of electronic or optical device for the average LVA user.<sup>21</sup> Due to the increasing importance of cost-effectiveness, some rehabilitation centers applied strict criteria to the provision of CCTVs. For instance, the Department of Veteran Affairs (USA) only loaned CCTVs to patients with a reading rate of at least 30 wpm or, when exceeded, to those patients who showed an increase in reading speed of at least 50% over other optical aids. Furthermore, patients had to be able to read for 30 consecutive minutes or, if exceeded, show an increase in duration of 100% over other LVAs. Other provision criteria were: the ability to write an address on an envelope, to operate the device independently, and to use the CCTV for writing.<sup>6;9-11;22;23</sup> In the Netherlands, such criteria do not exist and CCTVs are prescribed to anyone who might benefit from such a device. Therefore, *Chapter 2* evaluates the prescription of LVAs by the two types of rehabilitation services in the Netherlands.

#### Summary of the results

The non-randomized prospective cohort study showed a relatively large difference in the numbers and types of LVAs prescribed by optometric and multidisciplinary services. Optometrists prescribed significantly more LVAs per person: mean difference (MD) 0.7. Furthermore, they tended to prescribe the more technical and complex optical aids, such as telescopic and glare-protective devices, whereas multidisciplinary rehabilitation centers (MRCs) prescribed more non-optical devices such as fluorescent lamps. Irrespective of which service was used, it was found that when visual acuity (VA) decreased, the need for LVAs that offer high magnifications increased. Therefore, CCTVs were mainly prescribed to patients with severe vision loss (VA <0.05 Snellen). Sixteen percent of all LVAs were CCTVs, just slightly less than near addition (19% of all LVAs). CCTVs were responsible for the major proportion of total costs of LVAs.

## Methodological limitations and future research

However, our study had some limitations: for instance, random assignment of the patients to one of the two types of low-vision services would have allowed to draw some conclusions about the value of the low-vision services. Instead, the hospitals involved in the study referred patients to either an optometric service or to a multidisciplinary service according to their standard practice. Nevertheless, confounding by indication was expected to be marginal. Furthermore, the results were adjusted for numerous (and from our perspective the most important) potential confounders.<sup>24</sup> However, some confounders were not assessed and could not be adjusted for: e.g., (mobility-related) physical performance and certain psychological traits. Note that the study protocol does not provide directions for referral of individual patients, as some patients might derive more benefit from an optometric service (e.g., patients with a need for reading aids only) whereas others might prefer the more holistic approach of an MRC (e.g., patients with more complex needs involving hobbies for which they may need multiple aids and instructions). Moreover, the study was based on secondary data analyses and was conducted at only one optometric service and at one MRC. Therefore, differences among the various optometric and multidisciplinary services in the Netherlands were not assessed, but could be a topic for future research. Furthermore, it is advisable to evaluate the (cost-)effectiveness of both services, and of the different types of LVAs and training programs in the use of these aids. Moreover, it is worthwhile to identify which patient characteristics are related to efficient use of LVAs, especially since some LVAs (such as CCTVs) are more expensive than others.<sup>21</sup> Information on all these topics will enable low-vision specialists to better advise patients as to what can be expected from the LVAs that are prescribed.

## **Feasibility of the Radner Reading Charts in low-vision patients**

### Background

The present thesis describes the effectiveness of a standard training program in the use of CCTVs. This study attempted to capture the whole experience of patients with the use of their CCTV by evaluating several outcome measures such as reading performance, task performance in daily living, and the patient's perceived quality of life.<sup>24</sup> However, reading speed was the primary outcome of previous studies on training in the use of CCTVs.<sup>6;9-18</sup> Therefore, to facilitate interpretation of the results and allow comparisons to be made with data from other studies, the main outcome measure of this thesis was also considered to be reading speed.

The use of standardized tests is important to obtain reading speed. Almost immediately before performing our effectiveness study, a new standardized test to simultaneously measure reading acuity and reading speed became available in the Dutch language: the Radner Reading Charts (RRCs).<sup>25;26</sup> This test is also available in German, English, Spanish, Swedish, Turkish, Hungarian and French.<sup>27</sup> The RRCs are based on the same principles as the Sloan M Charts<sup>28</sup> and the Minnesota Reading Chart (MNread),<sup>29</sup> this latter chart was used in at least three studies on CCTV reading

performance.<sup>20;30;31</sup> However, the RRCs have an advantage over other national<sup>32</sup> and international<sup>28;29;33;34</sup> reading charts in that they use 'sentence optotypes', which are highly comparable sentences in terms of number of words, word length, position of words, lexical difficulty and syntactical complexity.<sup>35</sup> Studies on the German and Dutch RRCs have shown a high inter-chart and test-retest reliability in patients with normal to low vision.<sup>36;37</sup> However, because both latter studies focused on patients with macula disease only and excluded other causes of low vision, it was unclear whether the RRCs were feasible for patients with low vision caused by various eye conditions, in addition to macula disease. Since many low-vision patients have reduced reading ability they are the prime candidates for low-vision devices such as CCTVs, and the feasibility of a reading chart for these patients was of major interest.

### Summary of the results

The RRCs showed a high inter-chart and test-retest reliability of variables which can be obtained with the charts, such as reading acuity (uncorrected and corrected for reading errors), reading distance vs. reading acuity ratio, and maximum and average reading speed. For these variables the largest part of the variance was explained by the individual subject (86-89%), whereas the chart accounted for only 0 to 0.8% of the variability. Only critical print size (CPS) had a poor to moderate reliability (31-62%) when calculated in two common ways. Although these results were similar to previous studies which investigated the reliability of the RRCs,<sup>36;37</sup> patients with low vision due to various eye conditions showed an increased variability of the measurements compared to these studies. Therefore, taking into account the variation within and between patients, it can be considered a strength of the charts that even in this heterogeneous population they yielded excellent results and appeared to be feasible to determine treatment effects.

### Methodological considerations and future research

Low-vision patients included in the study showed fluctuating results in reading performance, both within and between the two sessions, leading to an increased variability. More studies are needed to elucidate whether the variability is a function of the severity of the visual impairment, or whether variation is caused by including various eye diseases (e.g. maculopathy, diabetic retinopathy, glaucoma, and cataract). Furthermore, the considerable variation in repeated measurements from the same subject indicates a moderate reproducibility and repeatability,<sup>38</sup> which seems to be in conflict with the high inter-chart and test-retest reliability. However, the satisfactory level of reliability was considered to depend on how a measure is being used. Since group research is often concerned with the size of correlations and with differences in means for experimental treatments, a reliability of 80% is adequate.<sup>39</sup> Therefore, the charts are considered feasible to evaluate reading performance in the present RCT to evaluate the effectiveness of training in the use of CCTVs in low-vision patients, as the inter-chart and test-retest reliability was 86-89% for all variables (except for the CPS). However, when decisions with respect to specific test scores are made about

an individual subject, a reliability of 90% is the minimum that should be tolerated, and a reliability of 95% should be considered the desirable standard.<sup>39</sup> Future studies are needed to establish the clinical value of the CPS and its exact definition.<sup>40;41</sup> (As it is possible to enlarge print with a CCTV, measuring CPS will not be part of the effectiveness study). In our study, the fixed reading distance of 40 cm might (in part) be responsible for the increased variability and may have negatively influenced the reproducibility and repeatability, as 11 patients could not read the charts from this distance. Therefore, because the selected distance may have been suboptimal for low-vision patients, this is considered a flaw of the study. In the design of the RRCs it is possible to correct visual acuity for reading at a shorter distance, which is recommended for future studies with low-vision patients. This approach was used in the RCT on the treatment effects of CCTV training (i.e., in the main chapters of this thesis). However, the problem remains that patients who suffer from severe vision loss show large differences in acuity from one measurement to another,<sup>42</sup> as well as greater variability in reading speed.<sup>40;41</sup> If a high reliability of measurements is required in individual low-vision patients it is recommended to let patients read two or three of the RRCs in one session and then to average the results; this will further enhance the reproducibility and repeatability of the measurements by a factor of  $\sqrt{2}$  and  $\sqrt{3}$ , respectively. As the RRCs are highly standardized compared to the Dutch LEO reading chart and the MNread (not available in Dutch), it is expected that the RRCs will also be more reliable. However, because our study did not compare results obtained with the different charts, this conclusion may be premature. Future research is necessary to assess the value of each of the charts.

## Main chapters

This thesis describes the development of a training program in the use of CCTVs, and the performance of a randomized controlled trial in which the effectiveness of the training program was tested in 122 patients referred to multidisciplinary rehabilitation centers (*Chapter 4*). Outcomes were reading performance (to gain insight into effective use of the CCTV; *Chapter 5*), quality of life (to understand how patients perceive their quality of life with regard to vision-related issues; *Chapter 6*), and task performance in daily living (to gain insight into task and goal achievement in daily living; *Chapter 7*) before and after the rehabilitation program, and compared between groups of patients who received the program and those who did not.

### Effects of a standard training in use of CCTVs in visually impaired adults

#### Background

Vision loss is a growing medical and social problem. In industrialized countries this loss is mainly caused by age-related diseases and very often no cure can be expected. Therefore, low-vision rehabilitation remains an important treatment option for visually impaired patients.<sup>43</sup> The aim of visual rehabilitation services is to improve visual ability, to contribute to being independent in daily living, and to be able to participate in society.<sup>44;45</sup> Considering the increasing costs and restricted budgets in health care, patients are stimulated to maintain their independence and to participate in society for as long as possible.<sup>45</sup> Furthermore, from a cost-effectiveness point of view, evidence-based care has become increasingly important for both the government and health insurance companies. Also, from an ethical point of view, some argue that it would be undesirable to provide a rehabilitation program without knowing the effectiveness of such a service.<sup>46</sup> Recent studies have evaluated the effectiveness of low-vision rehabilitation services.<sup>19;24;47-51</sup> Longitudinal outcomes of low-vision rehabilitation of older patients referred to optometric and multidisciplinary services in the Netherlands, showed a lack of effects on most vision-related quality of life dimensions. Only patients referred to MRCs showed significant beneficial 5-month and 1-year effects on the 'Reading small print' dimension of the Low-Vision Quality of Life Questionnaire (LVQOL).<sup>24;47</sup> However, at 4-5-year follow-up this effect was not maintained.<sup>48</sup> Because the study did not include a control or placebo group, no conclusions can be drawn about the value of the low-vision services. In contrast, a multicenter RCT in the USA showed significant improvement in all aspects of visual function (obtained with the Veteran Affairs Low-Vision Visual Functioning Questionnaire) after low-vision rehabilitation.<sup>51</sup> Both studies mentioned the need to assess specific rehabilitation programs rather than the entire rehabilitation service, as the components contributing to the treatment effect were unknown. Another reason to assess the efficacy of specific programs might be to create the possibility of adjusting programs as required, to develop more evidence-based rehabilitation services. For this reason the rehabilitation services in the Netherlands were interested in the effectiveness of the CCTV training that they provided. However, the training

provided by the MRCs was not structured. Although some exercise books on training in the use of CCTVs existed within the Dutch MRCs, they were rarely used in daily practice and standardized protocols were lacking. Therefore, a standard training in the use of this device needed to be developed and tested in an RCT, to obtain an evidence-based training protocol. The development of the training protocol, and the design and methodology of the trial, are described in *Chapter 4*.

## **Methods**

Intervention: development of a protocol in the use of CCTVs

To develop a structured training program, information was collected by studying literature, observing training in the use of CCTVs, discussing the content of the training program with professionals, and organizing focus and discussion groups. Consensus on the final program was reached after sending the protocol twice to low-vision therapists involved in the study and occupied with CCTV training. The final protocol consists of various chapters, including several exercises in each chapter. The focus of the training protocol is on ergonomics, basic operation skills, reading, writing, looking at pictures and photographs, and performing hobbies. In accordance with previous studies, the duration of training was 60 minutes. However, we introduced a 15 to 30 minute break after the first 30 minutes, because most CCTV users are elderly and often have difficulty in maintaining concentration for a prolonged period, or experience fatigue. During the sessions, various reading and writing materials were available. Moreover, patients were actively trained in their home environment with their own CCTV and direct feedback was given. The frequency of training was once a week, and the number of sessions was dependent on the learning strategies of the individual patients. Training was given until the patient had practiced with every chapter, or until no further progress could be achieved.

Study design: a randomized controlled trial

To evaluate the effectiveness of the training program a multicenter RCT was conducted at nine sites of three Dutch MRCs. Low-vision specialists who prescribed CCTVs at the MRCs, screened patients for eligibility and invited them to join the study. Patients were randomized to either a treatment or control group using a computer-generated allocation scheme based on blocks of two, stratified by the nine sites. Both groups received the normal delivery instructions from the supplier. In addition, patients in the treatment group received training from low-vision therapists of the MRCs. For ethical considerations, patients in the control group were offered the training program after their follow-up measurements were completed.

Outcome measures

After the delivery of the CCTV (before the start of the training program in the treatment group) and at 3-months follow-up, measurements were performed to evaluate changes in reading performance, quality of life, and tasks performance in daily living.

Training and practice in the use of CCTV are reported to significantly improve reading performance, e.g. reading speed and reading duration.<sup>4;6;9-18</sup> Reading performance analyses are useful to measure the impact of visual disability and the success of recommended therapy.<sup>35</sup> As reported by Lagrow et al., no dramatic changes in reading rates were expected to occur after the initial effect of introducing a CCTV without training (although practice often becomes a more influential factor over time). In contrast, it was expected that even with minimum instructions subjects would significantly increase their CCTV reading rate.<sup>4</sup> Therefore, the main outcome measure was reading performance, which was obtained by measuring reading acuity, maximum and average reading speed, and the number of reading errors using the Radner Reading Charts.<sup>27</sup> Furthermore, column-tracking time and technical reading were assessed with the Test Technical Reading 345678.<sup>52</sup> Videotapes of all measurements were independently rated by two investigators.

In addition to reading performance, it is important to investigate the outcomes of training on subjective measures such as quality of life (QOL), depression or adjustment to vision loss. In general, there is little evidence for the effect of low-vision rehabilitation or specific skills training (such as learning how to use a CCTV) on these outcome measures. An important reason for measuring health-related QOL, also in low-vision rehabilitation, is the growing interest of governments and health insurance companies in these outcome measures as parameters for quality of care. Furthermore, better scores on these types of outcomes may indirectly be the result of improved ability to perform certain skills, such as reading. Another reason to investigate subjective outcome measures is that feelings of depression may interfere with low-vision rehabilitation outcomes. Depression can affect a person's learning capacity or ability to retain information, and may result in disturbance of thought processes, difficulty in making decisions, or difficulty in orienting towards achieving goals.<sup>53</sup> Vision-related QOL was measured with the Low Vision Quality of Life questionnaire (LVQOL).<sup>48;54</sup> Other subjective outcome measures, i.e., adjustment to vision loss, depressive symptoms, and health-related QOL, were measured with the Adjustment to age-related Vision Loss (AVL) scale,<sup>55</sup> the Center for Epidemiological Studies Depression scale (CES-D)<sup>56</sup> and the EuroQOL 5-Dimensions questionnaire (EQ5D).<sup>57</sup> To facilitate interpretation of the results, it was decided to report summary scores on these questionnaires, after the internal consistency reliability was tested in our population.

Previous reading performance and QOL outcomes provided little information on how visually impaired patients experienced reading or performing other tasks in daily life, or to what extent their rehabilitation goals were met. According to a previous report, current low-vision services can restore most patients' ability to read at a level sufficient to meet the patients' goals.<sup>12</sup> However, to our knowledge, previous studies on outcomes of training in the use of CCTVs did not make an inventory of the patient's difficulties with certain tasks or goals, nor did they describe to what extent

these goals were met. Massof et al. noted that if the purpose of rehabilitation is to decrease disability and to monitor progress, then the outcome of rehabilitation should be measured at both goal and task level, as rehabilitation often occurs at task level and tasks are performed to serve certain goals.<sup>58</sup> The Activity Inventory is a questionnaire developed for this purpose.<sup>58;59</sup> The Dutch ICF version of this questionnaire<sup>60;61</sup> was administered at baseline and 3 months later. Patients rated the difficulty of goals that were important to them, and the difficulty of tasks nested under goals found to be both important and difficult. Difficulty scores of goals and tasks with a response of at least 60% were reported.

### Statistical analysis

Differences between the characteristics of patients in both trial arms, and between responders and non-responders, were analysed with  $\chi^2$ -tests and independent samples t-tests. Linear mixed modeling was used to assess treatment effects on reading performance and QOL of the present trial, defined as the treatment allocation x time interaction. Linear mixed models allow simultaneous comparisons of dependent observations within and between groups over time.<sup>62</sup> Analysis of treatment effects was based on the intention-to-treat principle. However, to compensate for patients who did not receive the intervention as allocated, analysis was repeated per protocol. In addition to analysing treatment effects, linear mixed models were used to estimate secondary effects of reading with and without a CCTV and/or change in reading performance from baseline to follow-up. As data at both time points add to the preciseness of estimates, all available data on measurements made at baseline and follow-up were used in the analysis. Furthermore, factors that could possibly influence outcomes were added to the mixed models to determine differential effects. To assess the effect of training on task performance, ordinal regression analyses were used to estimate cumulative odds ratios for the difficulty scores of goals. To estimate difficulty scores on tasks nested under goals found to be important and difficult, sum scores were analyzed using linear mixed models, in a similar way to assessing reading performance and QOL outcomes. Effect sizes were calculated for the treatment effects.<sup>63</sup>

### Response/non-response

Between April 2008 and August 2009, 168 patients were screened for eligibility and invited to participate in the study. Of the 122 eligible patients, 62 were randomized to the treatment group and 60 to the control group. After informed consent was obtained 8 patients discontinued the study prior to the baseline measurements on reading performance and task performance, and another 8 patients did not participate in the follow-up measurements on these outcomes. Therefore, reading and task performance was obtained in 114 patients at baseline and 106 patients at follow-up. Although patients were frequently reminded to return their QOL questionnaire, not all patients did so. Finally, of the 122 patients, 111 filled in the baseline and 92 the follow-up questionnaire (of which 3 did not have baseline measurements). Therefore,

QOL outcomes of 114 patients were analyzed. However, some patients who did not return their questionnaire did participate in the reading and task performance measurements, and vice versa. Table 1 shows the number of patients in both trial arms on each of the outcome measures.

There were no significant differences in baseline characteristics between the patients in each treatment arm: mean age of the study population was 77.2 years, mean visual acuity 0.88 logMAR, and the primary cause of vision loss was age-related macular degeneration (68%). However, there was an age difference between patients who completed the study ( $n=106$ , mean age 76.5 years) and patients who discontinued during the study ( $n=16$ , mean age 82.6 years;  $p < 0.01$ ).

**Table 1. Overview of respondents on each of the outcome measures**

Outcome	Allocation	Randomized	Discontinued before baseline	Completed follow-up	Received assigned intervention	Did not receive assigned intervention	Unknown	Intention-to-treat analysis	Per-protocol analysis
Reading performance	Treatment	62	3	55	49	6	4	59	51
	Control	60	5	51	52	2	1	55	58
Quality of life	Treatment	62	5	49	47	5	5	49	48
	Control	60	3	43	51	1	5	43	56
Task performance	Treatment	62	3	55	49	6	4	59	Not performed
	Control	60	5	51	52	2	1	55	Not performed

## Results: effects of training in the use of CCTVs

### Reading performance

Intention-to-treat analysis did not yield any treatment effects of CCTV training on reading performance (i.e., there was no difference in reading acuity, reading speed, reading errors, column-tracking time, and technical reading between the treatment and control group). However, reading performance largely improved in all patients when reading with CCTV was compared to reading without CCTV; reading acuity improved by (mean) 0.93 logRAD, maximum reading speed increased by (mean) 15 wpm, and the number of reading errors decreased by (mean) 0.33 mistakes. Patients in both groups also showed improvement in CCTV performance from baseline to follow-up on average reading speed, number of errors, and column-tracking time. However, since there were no significant differences in treatment effects between the two groups, most performance differences appear to be the result of introducing the device, not of training or practice differentials.

### Quality of life, depression and adaptation to vision loss

Results on the Low Vision Quality Of Life questionnaire (LVQOL) showed a significant improvement on the 'Adjustment' (MD -4.67 points, range 0-100) and 'Reading and fine work' (MD -28.8 points, range 0-100) dimensions of the LVQOL from baseline (patients had not yet received their CCTV) to follow-up (patients had received and used their CCTV). Patients from the treatment group perceived less problems on each of the dimensions of the LVQOL, less depressive symptoms (measured with the CES-D) and were more adjusted to vision loss (measured with the AVL) than patients in the control group (but these treatment effects were not significant). However, when corrected for patients who did not receive the intervention as allocated (i.e., per-protocol analyses), CCTV training proved to be effective on health-related QOL (measured with the EQ5D). Training protected patients from a decline in health-related QOL. Note, however, that the advantages of randomization are lost once deliberate changes are made to the initial random allocation. Therefore, the per-protocol results should be interpreted with caution.

### Task performance in daily living

All patients reported significantly less difficulty completing all goals and the investigated tasks with the use of their CCTV. However, there was no effect of treatment on the difficulty scores of goals as they were rated similarly in both groups. Although no treatment effect on the goal Writing was found, there was a treatment effect on the (mean) sum score of tasks nested under this goal (mean difference 2.3, range -4 - 4;  $p=0.005$ ), indicating that participants in the control group rated these tasks as more difficult to perform than participants who received training in the use of their CCTV. The odds of responding in a category  $\geq 1$  (at least some difficulty) rating the difficulty score of the goal 'Creative activities' in the control group was 3.02 times the corresponding odds in the treatment group, which was on the verge of significance. This means that there was a beneficial improvement from baseline to follow-up in the difficulty of achieving this goal in the treatment group compared to the control group. Furthermore, patients reported frequent use of their CCTV for a great diversity of tasks (e.g., correspondence, reading newspapers and magazines): 81% used their CCTV at least once a day, (mean) duration 68.9 (SD 62.5) minutes.

**Table 2. Effects of the randomized control trial on reading, quality of life and task performance.**

Outcomes	Treatment effect in unit of measurement	Effect size	Effect of receiving a CCTV in the total group	Effect size
Reading acuity (logRAD)	-0.03 (p=0.43) <sup>a</sup>	-0.15	-0.93 (p < 0.01) <sup>a*</sup>	-3.84
Maximum reading speed (wpm)	3.34 (p=0.56)	0.06	18.24 (p < 0.01) <sup>*</sup>	0.31
Average reading speed (wpm)	0.83 (p=0.81)	0.02	3.43 (p=0.06) <sup>*</sup>	0.08
Reading errors	-0.14 (p=0.27)	-0.13	-0.33 (p=0.04) <sup>*</sup>	-0.17
Column-tracking time (sec)	0.34 (p=0.83)	0.06	NO <sup>†</sup>	NO <sup>†</sup>
Words technical reading	0.66 (p=0.86)	0.02	NO <sup>†</sup>	NO <sup>†</sup>
LVQOL - Basic aspects	-6.22 (p=0.07) <sup>a</sup>	-0.34	-1.97 (p=0.26) <sup>a</sup>	-0.11
LVQOL- Adjustment	-6.56 (p=0.14)	-0.30	-4.67 (p=0.04) <sup>*</sup>	-0.21
LVQOL - Reading and fine work	-7.56 (p=0.23)	-0.32	-28.83 (p < 0.001) <sup>*</sup>	-1.20
CES-D	-2.12 (p=0.20)	-0.24	-1.15 (p=0.16)	-0.13
AVL	3.44 (p=0.13)	0.36	0.97 (p=0.39)	0.1
EQ-5D	0.05 (p=0.15)	0.26	-0.002 (p=0.88)	-0.01
	<b>Cumulative odds ratio [95% CI]</b>		<b>Z</b>	
Goals				
• Reading	1.43 [0.72 ; 2.86] <sup>b</sup>		-6.47 (p < 0.001) <sup>c*</sup>	
• Writing	1.41 [0.65 ; 3.09]		-3.96 (p < 0.001) <sup>*</sup>	
• Personal administration	1.10 [0.39 ; 3.11]		-3.87 (p < 0.001) <sup>*</sup>	
• Manage finance	0.69 [0.23 ; 2.06]		-3.30 (p=0.001) <sup>*</sup>	
• Follow a schedule	2.51 [0.90 ; 6.99]		-3.18 (p=0.001) <sup>*</sup>	
• Personal correspondence	1.19 [0.45 ; 3.13]		-2.25 (p=0.024) <sup>*</sup>	
• Personal healthcare	0.36 [0.88 ; 2.31]		-2.16 (p=0.031) <sup>*</sup>	
• Follow the news	0.43 [0.13 ; 1.44]		-1.02 (p=0.307) <sup>*</sup>	
• Creative activities	3.02 [0.99 ; 9.25]		-2.67 (p=0.008) <sup>*</sup>	
Tasks				
• Reading	0.44 [-1.93 ; 2.80] <sup>a</sup>	0.07	-4.65 (p < 0.001) <sup>c*</sup>	
• Writing	-2.30 [-3.89 ; -0.71] <sup>*</sup>	-0.63	-4.72 (p < 0.001) <sup>*</sup>	
• Personal administration	0.11 [-1.53 ; 1.74]	0.03	-5.57 (p < 0.001) <sup>*</sup>	
• Manage finance	-1.25 [-3.06 ; 0.56]	-0.34	-3.49 (p < 0.001) <sup>*</sup>	
• Personal correspondence	0.88 [-0.67 ; 2.43]	0.20	-5.30 (p < 0.001) <sup>*</sup>	

<sup>a</sup> Mixed model analyses

<sup>b</sup> Cumulative odds ratios, except for the goal 'Personal Healthcare' for which a proportional Hazard ratio was determined

<sup>c</sup> Wilcoxon signed ranks test

<sup>\*</sup> Significant at the p < 0.05 level.

<sup>†</sup> NO not obtained without CCTV

## Discussion

A recent review reported that high-quality research on the outcomes of low-vision service provision is very limited. Only a few RCTs are available, whereas these were considered to provide the highest quality of evidence. The inclusion of a control group was recommended because this increases confidence that the observed outcomes in the treatment group are dependent on the intervention studied and not on other factors. Furthermore, it was recommended to incorporate masking to ensure that the trial is sufficiently powered, and to focus on consensus-driven outcomes.<sup>19</sup> The design of the present RCT incorporated most (if not all) of these recommendations.

It was expected that the intervention would lead to an improved reading performance (i.e., higher reading speed), improved QOL, and less difficulty in performing tasks and achieving goals in daily living. Although large effects on these outcomes were found, (i.e., reading performance [reading acuity, reading speed, and the number of reading errors], QOL [Reading and fine work dimension of the LVQOL] and tasks performance in daily living [all goals and tasks] largely improved in all patients when reading with CCTV was compared to reading without CCTV) analysis failed to yield undisputed effects of training in the use of the device. Similarly, in the RCT of Pearce et al., patients receiving device handling training showed a similar improvement in functional ability compared to patients who only received a low-vision aid without additional training in its use.<sup>64</sup> However, their study did not include electronic magnifiers. We expected that handling a relatively complex electronic device would require at least some training. In contrast, Mintz et al. stated that one advantage of the CCTV over other optical aids is that no specific training is required in its use, other than simple technical skills needed.<sup>65</sup> Most patients (89%) received training in these skills from the suppliers delivering the CCTVs, and these instructions were well received by most patients. Therefore, these instructions, in addition to effectively prescribing a CCTV to visually impaired patients, might be sufficient to improve reading performance, as well as QOL and task performance in daily life. Also Strong et al.<sup>66</sup> and Huber et al.<sup>67</sup> found a positive psychological impact of CCTV devices in patients receiving a CCTV without additional training in its use.

Although our study yielded two positive treatment effects, these were small and inconsistent. First, intention-to-treat analysis showed no effects of training in the use of the device on reading performance and QOL. However, when corrected for patients who did not receive the intervention as assigned (per-protocol analysis), CCTV training had a protective effect on a decline in health-related QOL. In general, there is little evidence that low-vision services improve generic health-related QOL.<sup>19</sup> Furthermore, the training program focused on reading and not on health-related aspects. Therefore, one may not expect a treatment effect on this subjective outcome and it can be assumed that mechanisms other than reading performance may have contributed to the treatment effect, e.g., the attention given by the trainer. However,

Reeves et al.<sup>46</sup> did not find a Hawthorne effect between patients who received conventional low-vision rehabilitation, and low-vision rehabilitation enhanced by home visits from a rehabilitation officer or a community care worker (the latter served as a control for contact time with patients). Second, a treatment effect on tasks serving the goal 'Writing' was found; however, in apparent contradiction, this did not result in the treated patient perceiving completing the goal 'Writing' as being less difficult. Therefore, the actual treatment effect did not seem to be confirmed. Both these findings might be attributed to multiple testing as significance was set at the  $p=0.05$  level and 5% of the comparisons made would then be significant based on chance alone.

### Comparison with previous study findings

The findings of our study seem to disagree with previous studies on CCTV performance (in the USA) that did find an effect of training. Variations in results may have been caused by differences in organizational structures, training strategies, and patient characteristics. For example, outpatient rehabilitation centers typically provide minimal reading training for either optical aids or CCTVs.<sup>8</sup> In contrast, in residential programs more extended training and practice sessions are scheduled. A recent RCT showed that outpatient low-vision rehabilitation was effective in improving visual ability at lower costs compared to inpatient rehabilitation.<sup>50;51;68</sup> However, when adjusted for baseline differences, the inpatient program showed significant improvement over the outpatient program.<sup>19</sup> Furthermore, both programs focused on more than CCTV training alone. Typically, more than one low-vision aid was prescribed and home-adjustments were made. As reading training is a process rather than a single event,<sup>8</sup> the minimal training (mean 2 sessions, range 1-7) offered in our study might have led to less impressive results. Similarly, in the studies of Goodrich et al., brief training did not provide as great an increase in reading speed as did extended training.<sup>8;9;15</sup> There may also be a difference in patients' characteristics between inpatient and outpatient services. Patients in inpatient services may have more severe vision loss (mean 0.97 to 1.0 logMAR) compared to patients in outpatient services (mean 0.88 logMAR in our study). Training might be more effective in patients who are more severely impaired; however, differences in acuity compared to our study are small and might not be significant. In a study by Goodrich et al., a group with similar acuity (0.85 logMAR) to that in our study population showed less progression in reading ability when undergoing brief training compared to groups with lower visual acuity (0.95 and 0.99 logMAR) undergoing extended training. However, when extended training was offered to the first group, reading ability restored to the same level as in the extended groups.<sup>6</sup> Therefore, differences in results when comparing our study with others are thought to be mainly caused by differences in the extensiveness of the programs. Also, baseline reading speed in our study (mean 100 wpm) may have been close to the maximum reading speed that could have been achieved since, in the study of Lowe et al., under the best conditions with regard to window width and character size, patients read at a similar speed (mean 100 wpm).<sup>18</sup> Furthermore, 100

wpm is even more than normally-sighted elderly patients aged  $\geq 75$  years can read,<sup>18</sup> which suggests that patients may have reached a reading ceiling with their CCTV. It seems a great advantage of the CCTV that, even without training in its use, patients can read at levels even faster than normally-sighted peers. This might be explained by the fact that CCTVs can beneficially affect other factors that might reduce the reading rate in elderly patients, such as low-contrast vision and illumination.

From the studies that concentrated on task performance with stand-mounted CCTVs, to our knowledge only Watson et al. also focused on improvement of reading ability from the patient's perspective.<sup>23</sup> In their study (in the USA) all patients reported improvement in reading, whereas in our study 64% subjectively rated some level of improvement, and 13-34% showed no improvement or even deterioration in reading ability. This might be explained by their patients receiving about 20 hours of training; however, training effects were not reported as training was not the subject of their study. Furthermore, patients needed to discriminate between the difficulty scores of reading with and without CCTV at one time point (i.e., 12-24 months after provision) and may have had trouble reproducing the level of difficulty in reading without the device. Another reason for the difference in results might be that CCTVs in the USA were only provided to patients who reached an initial 50% increase in reading speed and/or showed an extended reading duration with the CCTV compared with optical aids,<sup>23</sup> whereas such performance criteria/conditions for prescribing CCTVs do not exist in the Netherlands.

Various studies have investigated usage rates of low-vision aids. Watson et al. reported that 85% of all prescribed LVAs were found at least somewhat helpful after 12-24 months.<sup>23</sup> Harper et al found that 87% of patients with macular degeneration regularly used their device, and 65% of patients used their device at least once a day.<sup>69</sup> In a study by Leat et al. 81% of patients used their LVA at least once a day.<sup>1</sup> Another study on CCTV usage also reported continued use of CCTVs two years after provision, with 87% of patients demonstrating effective use.<sup>11</sup> In our study 81% of our participants used the CCTV at least once or more a day, and 16% once or more a week, for (mean) 68.9 minutes. Maximum consecutive use was 360 minutes. Although the frequency of use was comparable to the mentioned studies, the CCTV was used for a greater diversity of tasks compared to those studies. Similarly, in an earlier report by Goodrich et al., reading correspondence was most frequently reported,<sup>14</sup> followed by reading newspapers, magazines and books. The percentage of patients who used their CCTV for reading newspapers, books, and periodicals, as well as writing letters or looking at photographs, has almost doubled compared to the study of Zabel et al. Therefore, it seems that in the Netherlands there has been an increased acceptance of the use of CCTVs since their study in 1980.<sup>70</sup> Such a change in acceptance might also be due to a cultural change, i.e., newer generations might be more comfortable using a CCTV as they are familiar with several other electronic devices such as televisions, computers, radios, etc.. Nowadays, patients may need less training or instructions

than in most studies on CCTV performance which were mainly performed between 1980 and 2000 (the latest studies were published in 2003 and 2004).

### Methodological considerations

Although it is a strength of the present study that an RCT design was used in a relatively large group, some study limitations need to be addressed. First, the study focused on CCTVs with stand-mounted cameras and displays. In contrast, there are 'mouse' style CCTVs as well as CCTVs with handheld or head-mounted cameras. Although it would have been interesting to include all these types of CCTVs, the stand-mounted types are most commonly prescribed in the Netherlands. Furthermore, for scientific reasons it can be considered a limitation that the training protocol was not standardized even further. Preferably, the frequency and the total minutes of training and practice with the assignments could also have been standardized. However, in daily practice it is important to personalize care, i.e., to adjust care to the rehabilitation needs and characteristics of the individual patient, for instance, their learning abilities, endurance and limitations due to co-morbidity.<sup>71</sup> Therefore, we decided to design the RCT in a pragmatic way, to be able to draw conclusions on treatment that would come close to daily practice, notwithstanding that there would be some variation between the patients. A benefit of this method is that the protocol could have been directly implemented once effectiveness had been proven, as the program was similar to daily practice in the MRCs.

In every study some problems have to be faced; for example, in our situation the recruitment of participants by the MRCs took longer than expected. Furthermore, one low-vision specialist at one of the MRCs did not invite patients that she thought needed CCTV training the most to join the study, to avoid the 'risk' that these patients might be randomized to the control group. Although this was discussed at the rehabilitation center, it remained unclear whether this site continued to include patients according to the standards of that low-vision specialist. Although statistical analysis with and without patients from this specific site yielded similar results, this selection bias may have led to an underestimation of the treatment effect and to a reduced generalizability of the results.

In retrospect, another factor that might have led to an underestimation of the treatment effect is that the study sample may have been too small to reveal significant results. Additional power analyses based on maximum reading speed were performed and revealed that over 5,000 participants would be required before the difference of 3.34 wpm between the treatment and control group could reach significance. The expected difference of 20 wpm (based on the results of Goodrich et al. in an inpatient population<sup>13</sup>) between treatment and controls on which the power analyses was based, may have been too optimistic in our (outpatient) study design.

Furthermore, reading performance and task performance were administered as soon as possible after delivery of the CCTV (mean 13 days), whereas in most studies the patient's first CCTV use was considered to be the baseline. We believe it is a strength of our study that we investigated effective use of CCTVs in the home environment (where the patients actually use their CCTV) rather than in a (laboratory) testing room.<sup>19</sup> However, our slight delay in baseline measurements may have caused the changes from baseline to follow-up to be minimal, which was confirmed by analyses of differential effects. An increase in time between delivery and baseline measurements caused a decrease in treatment effect. Therefore, some improvement in reading performance might have already accrued due to patients practicing with the device prior to baseline measurements. However, the differential effect was only found for average reading speed and was not confirmed in maximum reading speed, or any of the other reading or task performance outcomes in both groups. Therefore, the results of this study strongly suggest that there is no evidence for the benefit of training and that the improvement in reading ability mainly emerges from the patients practicing on their own.

The treatment effect may also have been underestimated because the patients were aware of the treatment allocation, which may have led patients in the control group to practice more than they might have done without this study, as they knew they would be retested after 3 months. Moreover, patients might have mentioned the ongoing trial to their CCTV suppliers, which may have resulted in a smaller treatment effect due to over-performance by the suppliers. Nevertheless, a treatment effect was still expected because, in the study by Goodrich et al., offering extended training in addition to basic instructions (based on the delivery instructions as offered in the private sector) increased the treatment effect.<sup>12</sup>

In addition, patients in our study used several additional LVAs which they had purchased themselves in stores or had received during previous visits to an MRC. As they could already use an LVA this might have minimized the effect of training. However, adding 'Use of an additional LVD' or 'Previous visit to an MRC' to the mixed model analysis did not cause a differential effect on any of the outcomes in either the treatment or the control group.

In the part of the analyses in which task performance in daily living was investigated, some difficulties were encountered. For example, the structure of the Activity Inventory allowed to skip questions on tasks and goals that patients perceived to be not important, not difficult or not applicable, which may have caused an underestimation of the treatment effect on task performance. Another limitation is that imputation techniques to compensate for missing data might have led to an underestimation of the sum scores of tasks. However, there was a large improvement from baseline to follow-up in both groups on all goals and the investigated tasks ('Following the

news' was not perceived as difficult at both time points), which was consistent with the reading performance and QOL outcomes of the present trial.

Not offering placebo training is perhaps another limitation of the study. It may have been preferable to offer placebo training to the control group, as an attention deficit in this group may result in a poorer outcome of rehabilitation. However, in the study of Reeves et al., having a control group for the contact time with patients did not lead to differences in task performance or quality of life.<sup>46</sup>

Finally, it should be noted that eccentric viewing training was not part of the protocol. Eccentric viewing training and perceptual learning might improve reading performance by improving the visual span<sup>72-77</sup> In a study by Nilsson et al., over 5 hours of perceptual training improved reading speed when wearing high-powered spectacles.<sup>72</sup> However, in the Netherlands, eccentric viewing training is not regularly offered to patients receiving low-vision aids. Furthermore, the evidence for perceptual training in CCTV training programs for mainly elderly patients is not very convincing. Goodrich et al. and Stelmack et al. offered eccentric viewing training with low-vision aids and, in contrast to the present study, found an effect of CCTV and outpatient training, respectively.<sup>15,51</sup> However, they reported that it remains unclear which part(s) of the programs used contributed to increasing efficiency in the use of CCTVs.

#### Future research

In general, more high-quality studies are needed in the field of low-vision. Randomized controlled trials are considered to offer higher evidence compared to other study designs.<sup>19</sup> Furthermore, more studies are needed to determine which components of training procedures are necessary, beneficial and actively contribute to increasing efficiency in using CCTVs compared to patients practicing on their own.<sup>18</sup> For example, it would be interesting to establish whether eccentric viewing improves reading speed with a CCTV. For rehabilitation practices, study results may imply that a thorough CCTV training may not be necessary, as the largest improvement in QOL was noted when receiving the device. However, as mentioned before, patients in the control group may have practiced more than they would have done without this study, because they knew they would be retested after 3 months and were aware of the treatment allocation. In future studies, exploring the long-term effect of attention of and conversation with a rehabilitation worker as control for the contact time that patients had with their trainer may be warranted to rule out a possible Hawthorn effect. Furthermore, it is worthwhile to explore whether patients practice more often when they know there will be a check-up test after 3 months, compared to patients who will have this check-up at shorter notice.

## Conclusions and general recommendations

Although the results of CCTV training were not convincing, this thesis contributes to the evidence in low-vision rehabilitation and to research in this field. Our work has shown that, in prescribing low-vision aids to visually impaired patients, there are differences between the optometric and multidisciplinary services. Optometric services tended to prescribe more aids per patient and more complex low-vision devices, whereas multidisciplinary services appear to have a more holistic approach. In both services, CCTVs were prescribed to severely visually impaired patients. Furthermore, the Radner reading charts appeared to be a reliable measurement tool to obtain information on reading performance in low-vision patients and was used in the effectiveness study. In addition, the process of delivering CCTVs became more transparent. The delivery instructions from the supplier seemed to be sufficient to effectively learn how to use a CCTV and were highly appreciated by the users.

In the main chapters it was shown that reading performance and task performance were significantly less difficult with the use of a CCTV than without the use of a CCTV. Furthermore patients reported significant improvement on the Reading and fine work and Adjustment dimension of the LVQOL when CCTV performance was compared to performance without a CCTV. However, the effects of training were small and inconsistent. Therefore, the benefit of training was not clearly proven and performance differences appear to be the result of introducing the device itself, and not of training or practice differentials. In general, there is good evidence that LVAs provided by low-vision rehabilitation services improve reading ability and are valued by the service users.<sup>19</sup> However, the improvement in reading ability was often based on clinical measurements and not on assessment of effectiveness outside the testing room, as in our study (at home). Furthermore, it is reported that the use of LVAs is associated with a reduction in disability and depression, which was also reflected in the results on QOL and task performance in daily living in our study.<sup>78</sup>

Goodrich et al. raised the concern that not providing CCTV training is an unethical practice because treatment of demonstrable value is being withheld from the patient.<sup>15</sup> Their study compared a number of training sessions and durations on reading performance, but no control group was included. Combining the primary and secondary outcomes of the present RCT, it may be concluded that the 'demonstrable value' of CCTV training is not sufficient and that empirical evidence now shows that training in the use of this device does not have additional value over delivery instructions and the patients practicing on their own. Also, Reeves et al. claim that one should be wary of proposing low-vision rehabilitation interventions without evidence of effectiveness.<sup>46</sup> In the future, all patients who receive a CCTV could be contacted to establish that the delivery instruction has been received by them, and that they know how to operate the CCTV. This check may reveal a maximum of about 1 out of 4-5 patients who require additional help. The consensus-based training protocol may

still provide a useful training strategy to effectively teach those patients how to use the CCTV. However, in general, multidisciplinary rehabilitation centers might consider investing their CCTV training resources in rehabilitation programs or services proven to be effective and contributing to other rehabilitation needs of this group of patients.

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