

The Effectiveness of Low-Vision Rehabilitation in 2 Cohorts Derived From the Veterans Affairs Low-Vision Intervention Trial

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Objective: To evaluate the effectiveness of low-vision rehabilitation in 2 cohorts derived from the Veterans Affairs Low-Vision Intervention Trial.

Methods: In a prospective study, we observed 44 participants randomly assigned to outpatient low-vision rehabilitation who did not receive additional treatment after the trial ended at 4-month follow-up and 56 participants randomly assigned to the waiting-list control group and thereafter to standard therapy. The outcome measures included visual ability domains (reading, mobility, visual information processing, and visual motor skills) and overall visual ability estimated from difficulty ratings using the 48-item Veterans Affairs Low-Vision Visual Functioning Questionnaire. Mean visual ability scores for the treatment and control groups were compared at baseline, 4 months, and 1 year. A mixed-effects model was used to test treatment effects between groups over time. Differences in visual ability mean scores from baseline to 1 year were compared between the 2 groups. Within-group changes in visual ability were compared from baseline to 1 year, from baseline to 4 months, and from 4 months to 1 year.

Results: At baseline, there were no significant differences in mean visual ability scores between groups. From baseline to 4 months, the treatment effects for all visual

ability domains and overall visual ability increased to a maximum in the treatment group ($P < .001$), whereas the mean scores (except visual motor skills) decreased in the control group ($P < .01$). From 4 months to 1 year, the differences became smaller. There was a loss of visual ability in reading and visual information processing (but not in visual motor skills, mobility, or overall visual ability) in the treatment group and a gain in all visual ability measures in the control group. Interactions of treatment and follow-up time in the mixed models showed the trend of treatment effects significantly changed over time from baseline to 1 year ($P < .001$) for all visual ability domains and overall visual ability. Both groups demonstrated improvement in visual ability from baseline to 1 year ($P < .001$) (except for mobility in the control group). Overall visual ability (but not other visual ability domains) improved more in the treatment group than in the control group ($P = .01$).

Conclusions: Visual ability improved significantly in both groups from baseline to 1 year. The Low-Vision Intervention Trial treatment effect is robust and well maintained for patients with macular diseases.

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AGE-RELATED EYE DISEASES are leading causes of chronic visual impairment in the elderly population.¹ Visual impairment increases the risk of major depression,²⁻⁵ injury,⁶⁻⁸ a decline in general health,⁹ and reductions in self-sufficiency and independence that may profoundly impact quality of life.¹⁰ Low-vision rehabilitation has the potential to restore functional visual ability. Although there is a consensus among service providers that low-vision rehabilitation helps many patients, to our knowledge, only a few multicenter randomized clinical trials have been performed that provide evidence of the benefits of low-vision rehabilitation.¹¹⁻¹⁶

The Veterans Affairs (VA) Low-Vision Intervention Trial (LOVIT) was conducted from November 2004 to November 2006 at 2 VA medical facilities (in Hines, Illinois, and Salisbury, North Carolina) to evaluate the effectiveness of an outpatient low-vision rehabilitation program for patients with macular diseases.¹⁶⁻¹⁹ A total of 126 veterans with visual acuity in the better-seeing eye worse than 20/100 and better than 20/500 were randomly assigned to low-vision treatment (treatment group) or a waiting list and thereafter to standard therapy (control group).

Patients randomly assigned to treatment were provided with 5 weekly low-vision therapy sessions (approximately

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2 hours per session) and a home visit from a visual therapist who taught them strategies for using their remaining vision and low-vision devices. Each patient was assigned 5 hours of homework per week. The homework was reviewed by the therapist with the patient at the next therapy session. Low-vision devices (refractive corrections, desktop closed-circuit televisions, monocular telescopes, teloupes, pocket magnifiers, stand magnifiers, reading glasses, reading stands, lamps for controlling illumination, and filters to control glare) were prescribed when appropriate and provided at no charge.

The primary outcome measure was the mean change in reading ability measured with the 48-item VA Low-Vision Visual Functioning Questionnaire (LV VFQ-48)^{20,23} for the treatment group compared with the control group. Secondary outcomes were changes in other visual domain scores constructed from subsets of items.^{16,17} The treatment group demonstrated significant improvement in all aspects of visual function compared with the waiting-list control group from baseline to 4-month follow-up (2 months after treatment was completed).¹⁶ The differences in mean changes between the 2 groups were large, 2.43 logits (95% CI, 2.07-2.77 logits) for visual reading ability; 0.84 logits (95% CI, 0.58-1.10 logits) for mobility; 1.38 logits (95% CI, 1.15-1.62 logits) for visual information processing; 1.51 logits (95% CI, 1.22-1.80 logits) for visual motor skills; and 1.63 logits (95% CI, 1.40-1.86 logits) for overall visual ability; and they were all highly significant ($P < .001$). The investigators concluded that the outpatient low-vision rehabilitation program was effective in improving functional visual ability.

METHODS

CONDUCT OF THE STUDY

After the trial ended at 4 months, the patients who were randomly assigned to the waiting-list control group were offered standard therapy. All control group participants received low-vision care from the VA when they were admitted to an inpatient blind rehabilitation center (BRC) or when they visited a local outpatient facility. Certified low-vision therapists who performed the LOVIT treatment also participated in the outpatient low-vision services provided for the control group. The control group did not receive the full LOVIT protocol, which included therapy, a home visit, and assigned homework that was reviewed by the therapist. Funding for transportation to the clinic visits was provided for study participants in the treatment group but not for those in the control group. The LOVIT treatment was provided during a 2-month period, whereas low-vision services for the control group were provided during the observation period after the trial concluded at 4 months and before the 1-year follow-up. The low-vision services that were provided, the location of service delivery, and the time to follow-up interview were not controlled during the observation period that ended at 1 year.

The VA LV VFQ-48,^{20,23} the 36-item Short Form Health Survey,²⁴ and the Center for Epidemiologic Studies–Depression²⁵ scale were administered by telephone at baseline prior to randomization, 4 months later, and at the 1-year follow-up by an interviewer who was masked to patient assignment. The Center for Epidemiological Studies–Depression Scale was used to screen for symptoms of depression. The 36-item Short Form

Health Survey was administered to assess domain scores for physical functioning, physical role limitations, bodily pain, vitality, social functioning, emotional role limitations, mental health, and general health. The other information on patient health status was collected during patient interviews.

Based on earlier observational studies of patients receiving services from the Hines BRC,^{26,27} our expectations were that patients in the control group would self-report more visual ability on the VA LV VFQ-48 after treatment and that the treatment group would experience some loss in visual ability during the time from 4 months to 1 year when they did not receive further treatment. However, visual ability in the treatment group would remain higher than in the control group. Increases in visual ability were expected to be significant in both groups from baseline to 1 year.

STUDY POPULATION

The 1-year follow-up interviews were completed by 51 patients randomly assigned to the treatment group and by 58 patients randomly assigned to the control group. Data were excluded for 7 treatment group participants who received additional low-vision rehabilitation between the 4-month and 1-year follow-ups and for 2 control group participants who did not receive low-vision treatment.

Table 1 presents the baseline characteristics and health status of the patients included in the follow-up study. There were no differences in any baseline variables between the 2 groups. Overall, 100% of the participants were white; 100% of the participants in the treatment group and 96.4% of the participants in the control group were male; the mean age was 78.9 years for the treatment group and 79.9 years for the control group. The mean distance visual acuity in the better-seeing eye was 1.1 logMAR for both the treatment and control groups. The patients excluded from the analysis were all male; one was African American. The mean distance visual acuity in the better-seeing eye for the excluded patients was 1.1 logMAR for the control group and 1.0 logMAR for the treatment group. The mean age of the excluded patients was 75.7 years for the treatment group and 56.5 years for the control group.

OUTCOME MEASURES

The VA LV VFQ-48,^{20,23} elicits patients' ratings of the difficulty they have performing each of a list of daily activities. The difficulty of each item was rated using the ordered response categories: (1) not difficult, (2) slightly/moderately difficult, (3) extremely difficult, and (4) impossible. Patients were also allowed to respond that they do not perform an activity for non-visual reasons. These values were treated as missing values in the analysis.

STATISTICAL ANALYSIS

Functional ability measures for each patient were estimated in logits (log odds) units by Rasch analysis of responses to all 48 items on the VA LV VFQ.^{20,23} Rasch analysis of responses to different subsets of items was used to estimate mean visual ability measures for reading, visual information processing, mobility, visual motor skills, and overall visual ability (from responses to all 48 items) for each administration of the VA LV VFQ-48. The linear relationship between log visual acuity and logits is estimated to be 0.13 logits per line of visual acuity on an Early Treatment Diabetic Retinopathy Study chart before rehabilitation.¹⁷ For each functional domain, a 2-sample *t* test was used to test the mean difference between the treatment group and the control group at baseline, 4 months, and 1 year. A mixed-

Table 1. Baseline Characteristics and Health Status of Patients

Characteristic	No. (%)		P Value
	Treatment Group (n = 44)	Control Group (n = 56)	
Age, mean (SD), y	78.9 (6.6)	79.9 (6.7)	.45
Male sex	44 (100.0)	54 (96.4)	.50
White	44 (100.0)	56 (100.0)	
Non-Hispanic origin	43 (97.7)	54 (96.4)	.99
Education, mean (SD), y	12.3 (2.5)	12.8 (3.5)	.38
Living situation			
Alone	7 (15.9)	14 (25.0)	.32
With family	36 (81.8)	41 (73.2)	
With nonfamily	1 (2.3)	0 (0.0)	
Nursing home/assisted living	0 (0.0)	1 (1.8)	
Retired	41 (93.2)	54 (96.4)	.65
Income, \$			
<20,000	10 (22.7)	19 (33.9)	.49
20,000-39,999	26 (59.1)	25 (44.6)	
40,000-59,999	4 (9.1)	7 (12.5)	
≥60,000	3 (6.8)	3 (5.4)	
Diabetes	8 (18.2)	18 (32.1)	.17
Pulmonary disease	8 (18.2)	16 (28.6)	.25
Arthritis	25 (56.8)	29 (51.8)	.69
Depression	7 (15.9)	10 (17.9)	.99
Hypertension	24 (54.5)	36 (64.3)	.41
Heart problems	24 (54.5)	37 (66.1)	.30
In need of assistance with walking	15 (34.1)	17 (30.4)	.83
Hand grip			
Strong	30 (68.2)	29 (51.8)	.28
Intermediate	13 (29.5)	25 (44.6)	
Weak	1 (2.3)	2 (3.6)	
Other hand problems	13 (29.5)	17 (30.4)	.99
Motion limitation	6 (13.6)	7 (12.5)	.99
Endurance limits	20 (45.5)	33 (58.9)	.23
Memory			
No memory problems	14 (31.8)	22 (39.3)	.69
Occasional periods of forgetfulness	29 (65.9)	32 (57.1)	
Frequently forgetful	1 (2.3)	2 (3.6)	
Age at which vision problem developed, y			
≤40	1 (2.3)	1 (1.8)	.09
41-60	5 (11.4)	1 (1.8)	
>60	38 (86.4)	53 (94.6)	
Vision fluctuates	10 (22.7)	9 (16.1)	.45
Difficulty hearing without hearing aid	24 (54.5)	28 (50.0)	.69
Uses hearing aid	10 (22.7)	14 (25.0)	.59
Habitual distance visual acuity in better-seeing eye, mean (SD), logMAR	1.1 (0.2)	1.1 (0.2)	.94
Habitual near acuity in better-seeing eye, mean (SD), No. of letters read at 20 cm (8 in)	30.1 (7.6)	31.8 (9.9)	.47
SF-36 physical component score, mean (SD)	42.5 (9.4)	43.0 (9.2)	.77
SF-36 mental component score, mean (SD)	55.1 (8.5)	53.8 (8.1)	.36
CES-D Scale score, mean (SD)	8.4 (6.9)	9.2 (8.8)	.56

Abbreviations: CES-D, Center for Epidemiologic Studies–Depression; SF-36, 36-item Short Form Health Survey.

effects linear regression was used to compare treatment effects between the 2 groups, including all 3 time points. The within-group changes for each cohort from baseline to 1 year, from baseline to 4 months, and from 4 months to 1 year were analyzed using paired *t* tests. Changes from baseline to 1 year between groups were compared using 2-sample *t* tests; $\alpha < .05$ was used as a significance criterion, which requires $P \leq .01$ when corrections are made for 5 comparisons of visual ability. Effect size, defined as the difference between groups in the mean changes divided by the pooled standard deviation of the changes, was also calculated to compare the relative magnitude of the mean changes in visual ability from baseline to 1 year in the treatment and control groups.²⁸

RESULT

TREATMENT

Low-vision services were provided for control group participants at a VA outpatient low-vision clinic or an inpatient BRC. Participants received a low-vision examination provided by an optometrist (100% of participants), education on eye disease diagnosis and prognosis (100% of participants), eccentric viewing training (88% of participants), instruction on the use of low-vision devices

(88% of participants), psychological counseling (12% of participants), and social work services (12% of participants). Low-vision devices were prescribed if appropriate and provided without charge. Information on other BRC services received by some patients (eg, the amount of therapy, the time and location of service delivery, or the low-vision devices prescribed) is not available.

OUTCOME

Our **Figure** presents the VA LV VFQ-48 mean scores for reading ability, mobility, visual information processing, visual motor skills, and overall visual ability in the treatment and control groups at baseline and 4-month and 1-year follow-ups. At baseline, there were no differences in scores between the treatment and control groups. At 4-month follow-up, the differences in mean scores between the 2 groups were highly significant ($P < .001$). There were significant differences in mean scores for all domains at 1 year ($P = .01$ to $P = .001$) except visual motor skills ($P = .24$). The treatment effects from baseline to 4 months for all domains and overall visual ability increased to maximum in the treatment group, whereas the mean scores decreased in the control group. After 4 months, the differences between the treatment and control groups became smaller, indicating loss of visual ability in the treatment group and a gain in visual ability in the control group.

The trend in treatment effects over time between the 2 groups was compared using mixed-effects models for overall visual ability and each domain. Interactions of treatment and follow-up time in the models were significant ($P < .001$), indicating that the treatment effect changed over time from baseline to 1 year for all domains and overall visual ability.

Table 2 presents the mean changes for all VA LV VFQ-48 domains and overall visual ability in logits from baseline to 1 year and the comparisons of the differences in mean changes from baseline to 1 year between the treatment and control groups. Both the treatment and control groups demonstrated significant improvement in visual ability domains (reading, visual information processing, and visual motor skills) and overall visual ability from baseline to 1 year ($P < .001$). Changes in mobility were significant for the treatment group ($P < .001$) but not for the control group. Compared with the control group, the treatment group had significantly greater improvement in overall visual ability ($P = .004$) but not in reading, visual motor skills, visual information processing, or mobility when adjustments were made for multiple comparisons.

Table 3 presents the gains in visual ability measured with the VA LV VFQ-48 in the treatment group from baseline to 4 months and the loss in visual ability that occurred from 4 months to 1 year when the treatment group did not receive any further treatment. Significant losses from 4 months to 1 year occurred in reading ability ($P < .001$) and visual information processing ($P < .01$), but not in mobility, visual motor skills, or overall visual ability when corrections were made for multiple comparisons. **Table 4** similarly presents the significant losses observed in overall visual ability and visual domain scores (reading, mobility, and visual information processing) but not in visual motor skills from baseline to 4 months for patients in the waiting-list

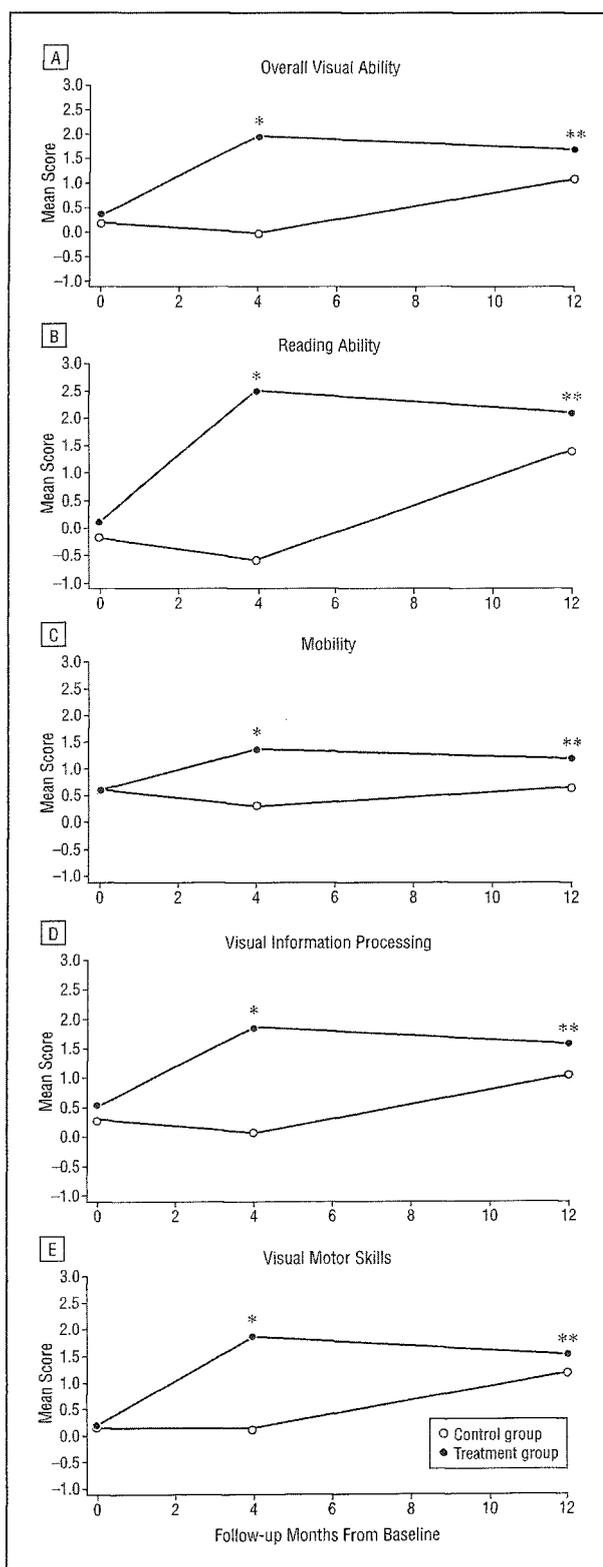


Figure. Mean scores over time from the 48-item Veterans Affairs Low-Vision Visual Functioning Questionnaire for overall visual ability (A), reading ability (B), mobility (C), visual information processing (D), and visual motor skills (E) in the treatment and control groups at baseline and 4-month and 1-year follow-ups. All plots use observed means at each time point. * $P < .001$ at 4-month follow-up. ** $P < .05$ at 12-month follow-up.

control group and significant gains in visual ability from 4 months to 1 year ($P < .01$) for all visual ability domains

Table 2. Mean Changes in Primary and Secondary Outcome Measures^a

VA LV VFQ-48	Mean (SD) Score ^b		Treatment vs Control		
	Treatment Group (n = 44)	Control Group (n = 56)	Difference (95% CI)	P Value	Effect Size
Reading ability					
Baseline	0.11 (0.84)	-0.18 (1.00)	0.38 (-0.05 to 0.08)	.08	0.36
Change	1.96 (1.08) ^c	1.59 (1.07) ^c			
Mobility					
Baseline	0.62 (0.84)	0.60 (1.09)	0.53 (0.16-0.90)	.05	0.58
Change	0.56 (0.92) ^c	0.03 (0.93)			
Visual information processing					
Baseline	0.51 (0.83)	0.28 (0.83)	0.31 (0.02-0.60)	.04	0.42
Change	1.08 (0.67) ^c	0.76 (0.78) ^c			
Visual motor skills					
Baseline	0.18 (0.95)	0.15 (0.90)	0.31 (-0.15 to 0.76)	.19	0.26
Change	1.34 (1.04) ^c	1.03 (1.23) ^c			
Overall visual ability					
Baseline	0.34 (0.74)	0.13 (0.8)	0.45 (0.15-0.76)	.004	0.59
Change	1.35 (0.76) ^c	0.9 (0.76) ^c			

Abbreviation: VA LV VFQ-48, 48-item Veterans Affairs Low-Vision Visual Functioning Questionnaire.

^aChange from baseline to 1 year.

^bHigher score indicates better ability or less difficulty in performing activities.

^cP < .001 for within-group change.

Table 3. Mean Changes in VA LV VFQ-48 Scores by Follow-up for Treatment Group

VA LV VFQ-48	Changes (Gains) From Baseline to 4 mo		Changes (Losses) From 4 mo to 1 y	
	Mean (SD)	P Value ^a	Mean (SD)	P Value ^a
Reading ability	2.40 (1.00)	<.001	-0.42 (0.77)	<.001
Mobility	0.73 (0.76)	<.001	-0.17 (0.71)	.12
Visual information processing	1.34 (0.68)	<.001	-0.26 (0.58)	<.01
Visual motor skills	1.68 (0.96)	<.001	-0.34 (1.04)	.04
Overall visual ability	1.62 (0.66)	<.001	-0.26 (0.71)	.02

Abbreviation: VA LV VFQ-48, 48-item Veterans Affairs Low-Vision Visual Functioning Questionnaire.

^aPaired t test for before and after change for 44 participants in the treatment group.

Table 4. Mean Changes in VA LV VFQ-48 Scores by Follow-up for Control Group

VA LV VFQ-48	Changes (Losses) From Baseline to 4 mo		Changes (Gains) From 4 mo to 1 y	
	Mean (SD)	P Value ^a	Mean (SD)	P Value ^a
Reading ability	-0.41 (0.51)	<.001	2.0 (1.13)	<.001
Mobility	-0.30 (0.73)	<.01	0.36 (0.78)	<.01
Visual information processing	-0.22 (0.54)	<.01	0.99 (0.70)	<.001
Visual motor skills	-0.03 (0.50)	.63	1.06 (1.03)	<.001
Overall visual ability	-0.21 (0.36)	<.001	1.11 (0.65)	<.001

Abbreviation: VA LV VFQ-48, 48-item Veterans Affairs Low-Vision Visual Functioning Questionnaire.

^aPaired t test for before and after change for 56 participants in the control group.

and overall visual ability after treatment was provided to the control group patients.

COMMENT

At baseline, there were no significant differences between the treatment and control groups in the baseline characteristics and health status of patients, the baseline

physical and mental component scores from the 36-item Short Form Health Survey, the baseline score from the Center for Epidemiological Studies–Depression Scale, or the baseline mean visual ability scores. The visual ability scores for all domains and overall visual ability increased to a maximum from baseline to 4 months in the treatment group, whereas the mean scores decreased in the control group, while participants remained on the waiting list during the

same time period. From 4 months to 1 year, after the control group received low-vision services, the differences between the 2 groups became smaller as the result of a small loss of visual ability in the treatment group and a large gain in visual ability in the control group. Interactions of treatment and follow-up time in mixed-effect models were significant for reading ability, mobility, visual information processing, visual motor skills, and overall visual ability, which indicates that the treatment effects for all domains and overall visual ability changed after the intervention for the 2 groups from baseline to 1 year.

The outpatient low-vision rehabilitation provided to the LOVIT treatment group under the study protocol and the ad libitum low-vision rehabilitation services provided to the control group significantly improved functional visual ability in veterans with moderate and severe vision loss due to macular diseases from baseline to 1 year. The improvement in overall visual ability for the treatment group was significantly larger than the improvement in the control group. The differences for the other visual ability domains were not significant. These treatment effects may be due to similarities or differences in the low-vision therapy or low-vision devices provided for patients in the treatment and control groups. However, details of the low-vision services provided for the control group are not available to fully explore the differences in outcomes.

The low-vision therapy and low-vision devices provided for the control group after the trial ended may have included critical elements of the LOVIT treatment protocol. Study participants in both groups received prescribed low-vision devices from the VA at no charge. The low-vision devices selected for use in the LOVIT and dispensed to patients in the treatment and control groups were those commonly prescribed at the Hines BRC. Because of the success of this program, which was reported in previous observational studies,^{20,26} therapy plans from the Hines BRC were shortened for outpatient service delivery and incorporated into the LOVIT treatment protocol. Certified low-vision therapists who performed the LOVIT treatment also participated in the outpatient low-vision services provided for the control group. Also, control group patients who were on the waiting list for admission to a VA BRC during their LOVIT participation received their low-vision care at the BRC.

There were also differences in service delivery between the 2 groups. The control group did not receive the full LOVIT protocol, which included therapy, a home visit, and assigned homework that was reviewed by the therapist. Funding for transportation to clinic visits was provided for study participants in the treatment group but not for those in the control group. The LOVIT treatment was provided during a 2-month period, whereas low-vision services for the control group were provided during the observation period after the trial concluded at 4 months and before the 1-year follow-up. The length of follow-up for individual patients in the control group is not known.

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