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Outcomes of the Veterans Affairs Low Vision Intervention Trial (LOVIT)

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Objective: To evaluate the effectiveness of a low-vision rehabilitation program.

Methods: A multicenter randomized clinical trial was conducted from November 2004 to November 2006 with a 4-month follow-up. A total of 126 patients were included, 98% of whom were white and male. The patients were referred from eye or low-vision clinics and blind rehabilitation centers with a visual acuity in the better-seeing eye worse than 20/100 and better than 20/500 and were eligible for Veterans Affairs (VA) services. Telephone interviews of patients were conducted in their homes before and after participation in an outpatient low-vision program at a VA medical care facility or a (waiting list) control group. The interviewer administering questionnaires by telephone was masked to patients' assignments. Interventions included low-vision examination, counseling, and prescription and provision of low-vision devices and 6 weekly sessions provided by a low-vision therapist to teach use of assistive devices and adaptive strategies to perform daily living tasks independently.

Main Outcome Measure: Change in patients' visual reading ability estimated from participant responses to the Veterans Affairs Low-Vision Visual Functioning Questionnaire (LV VFQ–48) reading items completed at baseline compared with 4 months after enrollment for the treatment and control groups. The secondary outcomes were changes in other visual ability domains (mobility, visual information processing, visual motor skills) and overall visual ability from baseline to 4 months estimated from VA LV VFQ-48 difficulty ratings for subsets of items.

Results: The treatment group demonstrated significant improvement in all aspects of visual function compared with the control group. The difference in mean changes was 2.43 logits (95% confidence interval [CI], 2.07-2.77; $P<.001$; effect size, 2.51) for visual reading ability; 0.84 logit (95% CI, 0.58-1.10; $P<.001$; effect size, 1.14) for mobility; 1.38 logits (95% CI, 1.15-1.62; $P<.001$; effect size, 2.03) for visual information processing; 1.51 logits (95% CI, 1.22-1.80; $P<.001$; effect size, 1.82) for visual motor skills; and 1.63 logits (95% CI, 1.40-1.86; $P<.001$; effect size, 2.51) for overall visual function.

Conclusion: The program effectively provided low-vision rehabilitation for patients with macular diseases.

Applications to Clinical Practice: At least 10 hours of low-vision therapy, including a home visit and assigned homework to encourage practice, is justified for patients with moderate and severe vision loss from macular diseases. Because the waiting-list control patients demonstrated a decline in functional ability, low-vision services should be offered as early as possible.

Trial Registration: clinicaltrials.gov Identifier: NCT00223756.

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LOW VISION, CHRONIC VISUAL impairment that limits everyday function, is 1 of the 10 most prevalent causes of disability in America.[1] Besides functional disability, low vision increases the risk of major depression,[2-5] injury,[6-8] and decline of general health.[9] Most cases of low vision are caused by age-related eye diseases.[10] Despite new treatments, the diseases that cause low vision are not curable.[11] In most cases, impaired vision cannot be corrected and rehabilitation is the only option for regaining lost function for the patient with low vision.

Low-vision rehabilitation aims to restore functional ability, the ability to perform tasks modulated by visual impairment. Low-vision service delivery includes assessment of each patient's remaining vision, needs, and goals; counseling; prescription of low-vision devices; and prescription of therapy to teach patients how to use assistive devices and adaptive strategies to perform daily living tasks independently. Most low-vision rehabilitation is provided as a private outpatient service. The American Academy of Ophthalmology, the American Optometric Association, and the American Occupa-

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tional Therapy Association advocate an interdisciplinary team approach in their preferred practice patterns.[12-14] In the typical situation, the optometrist or ophthalmologist provides the evaluation and management services and authorizes the treatment plan. The occupational therapist (or certified low-vision therapist) performs the functional and home evaluations and provides rehabilitative training in the clinic or the patient's home.[15,16]

Although there is a general consensus that low-vision rehabilitation is better than doing nothing, the few randomized controlled clinical trials of low-vision rehabilitation reported in the literature do not provide compelling evidence to support current practices.[17-20] Consistent findings from 7 observational studies[21-27] and 4 randomized controlled trials[17-20] that used outcome measures based on rating-scale questionnaires administered to patients showed that the effects achieved by interdisciplinary outpatient low-vision rehabilitation services were small. Observed effect sizes, defined as the difference in the mean changes divided by the pooled standard deviation of the changes,[28] ranged from 0.06 to 0.43 (average of 0.3 across studies).

In contrast to private outpatient services, the Department of Veterans Affairs provides intensive inpatient low-vision services as part of the blind rehabilitation programs offered to eligible patients in 10 blind rehabilitation centers throughout the country.[29] Patients with a visual acuity poorer than 20/100 in the better eye or binocular visual field constricted to less than 20° can be admitted to a regional Veterans Affairs (VA) blind rehabilitation center to participate in a program that usually runs for 4 to 6 weeks. The blind rehabilitation center program team includes nurses, a physician, an optometrist, a psychologist, a social worker, orientation and mobility specialists, rehabilitation teachers, low-vision therapists, and computer-adaptive training specialists. Low-vision services focused on vision enhancement (eg, use of magnifiers to read), vision substitution (eg, traveling safely using a long cane), adjustment counseling, recreational therapy, family education, and discharge planning are provided. An observational study of patients with low vision admitted to one VA inpatient blind rehabilitation center used a rating-scale questionnaire administered to the patient as the outcome measure and demonstrated an effect size of 2.1,[24] nearly 7 times the average effect size observed in studies of private outpatient low-vision rehabilitation services.

Evidence-based models of outpatient low-vision and blind rehabilitation services are needed for cost-effective service delivery and to provide alternate treatment options for veterans. The objective of the VA Low Vision Intervention Trial (LOVIT) was to develop and evaluate the effectiveness of an outpatient low-vision rehabilitation program for veterans with moderate and severe vision loss due to macular diseases.

METHODS

CONDUCT OF THE STUDY

LOVIT was conducted in an outpatient setting at 2 VA medical care facilities (Hines, Illinois, and Salisbury, North Carolina). The rationale for the study design and methods used in LOVIT are discussed in a previous publication.[30] The protocol and written informed consents were approved by the institutional review boards at both sites (Edward E. Hines Jr VA Hospital and the W. G. Hefner VA Medical Center). Each study participant gave written informed consent after the purpose and procedures of the trial were explained. Study oversight was provided by an independent data and safety monitoring committee and the VA Cooperative Studies Program Coordinating Center (Hines, Illinois).

STUDY POPULATION

The inclusion criteria for the trial were primary eye diagnosis in the better-seeing eye of macular degeneration, macular dystrophy, macular hole, or inflammatory disease of the macula; visual acuity in the better-seeing eye worse than 20/100 and better than 20/500; and eligibility for VA benefits. Exclusion criteria were no access to telephone; inability to speak English; previous recipient of comprehensive low-vision services; English literacy less than fifth-grade level; Telephone Interview for Cognitive Status[31] score of 30 or lower; history of stroke with aphasia; other health condition that would preclude follow-up; inability or unwillingness to attend clinic visits required for the study; severe hearing impairment that interferes with participation in telephone questionnaires; vitreous hemorrhage, serous or hemorrhagic detachment of the macula, clinically significant macular edema, or cystoid macular edema; and cataract extraction planned within the next 6 months.

PROTOCOL DESIGN

Potential LOVIT patients with macular diseases were screened for major inclusion and exclusion criteria by medical record review. Those who were eligible based on this review were interviewed by telephone and invited to a screening examination unless there was one or more reasons to exclude them. Additional eligibility screening was conducted by therapists, who enrolled the participants, in the low-vision clinic and during a telephone interview. Visual acuity was measured using the Early Treatment of Diabetic Retinopathy Study distance visual acuity chart[32] and the Lighthouse Near Visual Acuity Test[32]; English literacy was tested using the Dolch Word Test[33] and demographic data were obtained. The therapists, who also served as assessors, were trained and certified in measurement of visual acuity and performance of the reading test.

The following questionnaires were administered by telephone at baseline prior to randomization: 48-item VA Low-Vision Visual Functioning Questionnaire (LV VFQ–48),[24,34-36] Short Form–36 (SF-36),[37] Center for Epidemiologic Studies Depression Scale (CES-D),[38] and the Telephone Interview for Cognitive Status.[31]

Eligible consenting patients were assigned randomly to low-vision treatment or waiting-list control groups by Coordinating Center staff after the collection of baseline data. Patients in the treatment group received services from an optometrist and a low-vision therapist certified by the Academy for Certification of Vision Rehabilitation and Education Professionals that included low-vision examination (including correction of refractive error); education on the eye disease diagnosis and prognosis; low-vision therapy; and prescribed low-vision devices. The intervention addressed the most common goals of patients with low vision: seeing better at all distances, near spot-checking needs (eg, reading price tags), table reading (reading limited amounts of printed materials), long-duration reading, spot-checking at far and intermediate distances (eg, reading signs), long-duration distance viewing, and glare control.

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The protocol for low-vision therapy consisted of 5 weekly sessions (approximately 2 hours per session) at the low-vision clinic to teach strategies for more effective use of remaining vision and use of low-vision devices. In addition, 1 home visit was provided to teach environmental adaptations and to set up low-vision devices so that patients could practice using them in their homes. Each patient was assigned 5 hours of homework per week after each therapy session to practice performing everyday tasks using the low-vision devices. The homework was reviewed by the therapist with the patient during the next weekly therapy session.

Treatment for patients in the control group was delayed for 4 months, a typical time that other veterans with low vision might have spent on a waiting list for low-vision or blind rehabilitation services. The control group received bimonthly telephone calls from the low-vision therapists during the 4 months they were waiting for treatment. The treatment group also received bimonthly telephone calls during the follow-up period after their treatment was completed. The purpose of these calls was to keep patients engaged in the study to prevent attrition and to report adverse events.

Outcomes were assessed by telephone by a masked interviewer 4 months from baseline in the treatment and control groups. The questionnaires administered at the 4-month follow-up were the VA LV VFQ–48,[24,34-36] SF-36,[37] and CES-D.[38]

RANDOMIZATION

A computer-generated allocation schema based on permuted blocks with blocks of random sizes was generated at the Coordinating Center. The Coordinating Center staff did not release the assignment until the participant eligibility was confirmed and signed consent was obtained. Eligible patients were assigned randomly with equal probability to the treatment group or the waiting-list control group. The Coordinating Center staff communicated each patient's assignment to the sites by telephone. Randomization was stratified by distance visual acuity less than 20/500 to 20/250 and better than 20/250 but less than 20/100, and by study site.

MASKING

The patients and the clinical staff providing low-vision rehabilitation were aware of the treatment assignments. The interviewer administering the questionnaires by telephone was masked to treatment assignment. A script, approved by the institutional review board, was read by the interviewer to explain to each subject that the responses to the questionnaires were anonymous and confidential and that the patient should not disclose his or her group assignment during the interview. Disclosures were tracked. None were reported. Primary and secondary outcome data for individual participants or groups of participants were not disclosed to the investigators or clinical staff until the conclusion of the study.

ASSESSMENT OF OUTCOMES

The primary outcome measure was the change in visual reading ability estimated from participant responses to the VA LV VFQ–48 reading items completed at baseline compared with 4 months after enrollment for the treatment and control groups. The VA LV VFQ–48 has been validated in the low-vision population.[24,34-36] It consists of 48 items to describe daily activities representing 4 functional domains: reading, mobility, visual information processing, and visual-guided motor behavior.[24,34-36] Participants rated the difficulty of each item using the ordered response categories: (1) not difficult, (2) slightly/moderately difficult, (3) extremely difficult, and (4) impossible. Participants also were allowed to respond that they do not do the activity described in the item for nonvisual reasons. Such responses were treated as missing values in the analysis. A higher score indicates more ability (ie, less difficulty) in performing daily activities. Visual reading ability was chosen as the primary outcome measure because reading is one of the most frequently reported goals of patients with low vision and most low-vision devices are designed to be used for reading.[39]

The secondary outcomes were changes in other visual ability domains (mobility, visual information processing, visual motor skills) and overall visual ability from baseline to 4 months estimated from responses to subsets of items in the VA LV VFQ–48.

STATISTICAL ANALYSES

When planning the study, we considered an increase of 0.78-logit (equivalent to 31%) improvement in visual reading ability for the treatment group, as compared with the control group, to be the threshold for clinical significance.[30] This choice of a minimum acceptable treatment effect was based on previously published observations of a linear relationship before rehabilitation between visual ability (in logits) and log visual acuity.[40] A 0.78-logit improvement in visual ability would correspond to the functional improvement expected to accompany a 6-line improvement in distance visual acuity on an Early Treatment of Diabetic Retinopathy Study visual acuity chart.[30] These changes can be compared with changes in visual acuity using the *International Classification of Diseases, Ninth Revision, Clinical Modification* (*ICD-9-CM*) classification. Such an improvement would improve the functional ability of the subjects with the least severe visual impairment meeting the LOVIT inclusion criteria to a near normal level (20/40-20/60) but would improve the subjects with the most severe visual impairment meeting the LOVIT inclusion criteria only to a level equivalent to that of patients with moderate visual impairments (20/70-20/160).

LOVIT was designed to have a statistical power of 90% and to allow a type I error of 5% to detect a 31% increase in the primary outcome using a 2-sided *t* test. With an assumption of a 10% attrition rate, we estimated that 122 patients would be required. Statistical guidelines for early stopping were not used because of the low risk of the test intervention and the short duration of the study both for individual participants and overall. The interim report was sent to the data monitoring committee for review biannually.

The linear functional visual ability scores for each subject were estimated by Rasch analysis of responses to all 48 items and recorded as logits (log odds ratio).[24,36] Rasch analysis of responses to different subsets of items was used to estimate linear visual ability measures for each of the 4 functional domains. All comparisons of visual function were analyzed according to the intention-to-treat principle. Differences in the primary and secondary outcomes between treatment and control groups were compared using a 2-sample *t* test. The differences in changes in visual reading ability and other visual functions from baseline to 4 months were also assessed using analysis of covariance with an adjustment for baseline scores, age, and presence of vision fluctuation and age when vision problems developed. Within-group changes were tested by the paired *t* test. We used the last observation carried forward method in analyses of the primary and secondary outcomes if the outcome values were missing because assessments were not performed at interim points.[41] In addition, we compared the outcomes by assigning the lowest rank to the missing outcomes and applied the Wilcoxon rank sum test. The findings of the 2 methods of analysis were consistent. For exploratory purposes, we also conducted an as-treated analysis in which the outcomes were compared after excluding the 9 patients who did not complete the follow-up evaluation.

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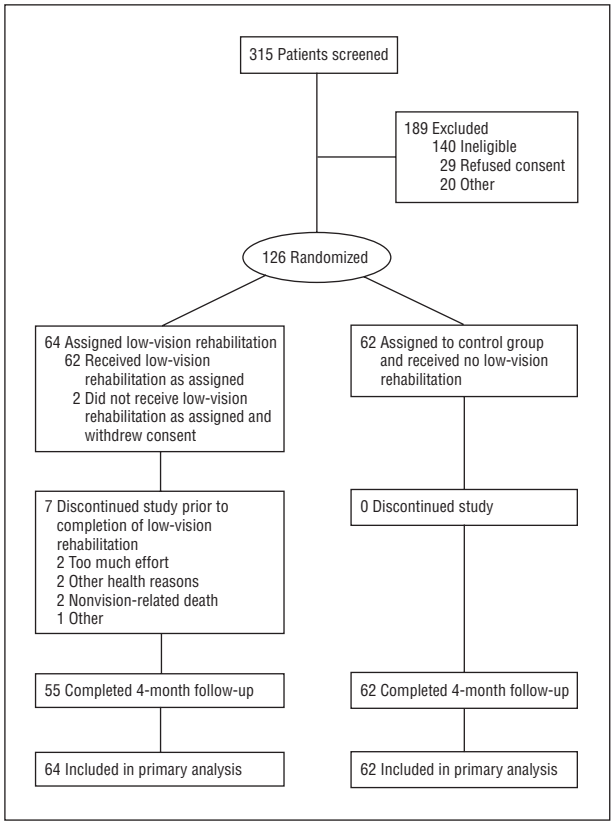

Figure 1. The flow diagram describes the flow of participants through each stage of the Veterans Affairs Low Vision Intervention Trial.

Planned comparisons of the primary and secondary outcomes between the treatment and control groups included those based on age group, level of baseline distance visual acuity, and reports of fluctuations in vision using *t* tests for 2 independent samples. The differences between the treatment and control groups in changes in quality of life measured by the SF-36 and CES-D from baseline to 4 months were also analyzed using the 2-sample *t* tests. All analyses were 2-sided and a *P* value less than or equal to .05 was considered to indicate statistical significance. We used SAS software (version 8; SAS Institute Inc, Cary, North Carolina) to perform all analyses.[42]

Effect size was calculated as planned to assess the magnitude of the differences in functional visual ability in relative units that can be compared across studies.

RESULTS

PATIENT CHARACTERISTICS

The first patient enrolled November 1, 2004. Accrual was completed July 31, 2006. The follow-up ended November 30, 2006. The flow of participants through each stage of the trial (screening, randomization, assignment, discontinuation of the study, study completion, and inclusion in the primary analysis) is described in **Figure 1**.

A total of 315 patients were screened, of whom 148 patients met the eligibility criteria. Of these patients, 126 were enrolled: 64 were assigned to the treatment group and 62 were assigned to the control group. The most frequent reasons for exclusion were the distance visual acuity in the better-seeing eye did not fall in the required range and the patient was unwilling or unable to participate in the study. Nine patients (14%), all in the treatment group, discontinued participation prior to completion of the study.

Baseline characteristics and health status of patients, changes in visual function measured with the VA LV VFQ–48 from baseline to 4 months, and mean changes in quality of life measured with the SF-36 and CES-D from baseline to 4 months are presented in **Tables 1**, **2**, and **3**. Overall, 98% were male and white; mean (SD) age was 78.9 (7.9); and those in the control arm were older (*P* = .04). Mean (SD)

Table 1. Baseline Characteristics and Health Status of Patients

	No. (%)	
	Training Group (n=64)	Control Group (n=62)
Age, y, mean (SD)	78.8 (7.8)	79.0 (8.1)
Male	63 (98.4)	60 (96.8)
Race		
White	62 (96.9)	61 (98.4)
African American	2 (3.1)	1 (1.6)
Ethnicity (non-Hispanic origin)	63 (98.4)	60 (96.8)
Education, y, mean (SD)	12.4 (2.7)	12.8 (3.5)
Living situation		
Alone	15 (23.4)	16 (25.8)
With family	46 (71.9)	45 (72.6)
With nonfamily	1 (1.6)	0 (0.0)
Nursing home/assisted living	2 (3.1)	1 (1.6)
Employment status		
Retired	59 (92.2)	59 (95.2)
Income, $		
< 20 000	14 (21.9)	22 (35.5)
20 000-39 999	34 (53.1)	27 (43.5)
40 000-59 999	8 (12.5)	8 (12.9)
>60 000	4 (6.3)	3 (4.8)
Diabetes mellitus	12 (18.8)	20 (32.3)
Pulmonary disease	13 (20.3)	19 (30.6)
Arthritis	38 (59.4)	31 (50.0)
Depression	11 (17.2)	11 (17.7)
Hypertension	36 (56.3)	41 (66.1)
Heart problems	33 (51.6)	42 (67.7)
Need walking assistance	21 (32.8)	18 (29.0)
Hand grip		
Strong	43 (67.2)	31 (50.0)
Intermediate	18 (28.1)	28 (45.2)
Weak	3 (4.7)	3 (4.8)
Other hand problems	18 (28.1)	18 (29.0)
Motion limitation	9 (14.1)	8 (12.9)
Endurance limits	34 (53.1)	36 (58.1)
Memory		
No memory problems	20 (31.3)	23 (37.1)
Occasional periods of forgetfulness	42 (65.6)	37 (59.7)
Frequently forgetful	2 (3.1)	2 (3.2)
Age at development of vision problem, y		
≤ 40	1 (1.6)	2 (3.2)
41-60	10 (15.6)	2 (3.2)
> 60	52 (81.3)	57 (91.9)
Vision fluctuates	19 (29.7)	11 (17.7)
Difficulty hearing without hearing aid	35 (54.7)	30 (48.4)
Use hearing aid	16 (25.0)	16 (25.8)
Habitual distance visual acuity in better-seeing eye, logMAR, mean (SD)	1.1 (0.2)	1.1 (0.2)

Abbreviation: logMAR, logarithm of the minimum angle of resolution.

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

	VA LV VFQ–48[24,34-36] Score, Mean (SD)[b]		Treatment vs Control	
	Treatment Group[c] (n=64)	Control Group (n=62)	Difference (95% CI)	Effect Size
Reading ability				
Baseline	0.32 (1.0)	–0.03 (1.1)		
Change from baseline to 4 mo	2.06 (1.2)[d]	–0.37 (0.55)[d]	2.43 (2.07-2.77)	2.51
Mobility				
Baseline	0.52 (1.0)	0.46 (1.1)		
Change from baseline to 4 mo	0.57 (0.7)[d]	–0.27 (0.7)[e]	0.84 (0.58-1.10)	1.14
Visual information processing				
Baseline	0.45 (0.9)	0.17 (0.8)		
Change from baseline to 4 mo	1.19 (0.8)[d]	–0.2 (0.5)[e]	1.38 (1.15-1.62)	2.03
Visual motor skill				
Baseline	0.23 (1.0)	0.09 (0.9)		
Change from baseline to 4 mo	1.47 (1.0)[d]	–0.04 (0.53)	1.51 (1.22-1.80)	1.82
Overall visual ability				
Baseline	0.35 (0.9)	0.13 (0.8)		
Change from baseline to 4 mo	1.43 (0.8)[d]	–0.2 (0.4)[d]	1.63 (1.40-1.86)	2.51

Abbreviations: CI, confidence interval; VA LV VFQ–48, Veterans Affairs Low-Vision Visual Functioning Questionnaire.
[a] Changes in visual ability (reading, mobility, visual information processing, visual motor skills, and overall ability) from baseline to 4 months measured with the VA LV VFQ–48 for the treatment and control groups. The unit of score is logit.
[b] Higher score indicates better ability or less difficulty in performing activities.
[c] Last baseline observation carried forward for 9 participants.
[d] $P \leq .001$ for within-group change.
[e] $P \leq .01$.

years of education were 12.6 (3.1). There was a marginal difference in baseline reading ability between the 2 groups.

TREATMENT

The total face-to-face time with the low-vision therapist averaged mean (SD) 10.46 (2.06) hours per patient in the treatment group. The mean (SD) total time for each patient to complete all homework assignments was 17.08 (8.9) hours. Closed-circuit television viewing systems and stand magnifiers were prescribed and dispensed to all 55 patients in the treatment group who completed the study. Other low-vision devices and spectacles prescribed and dispensed included monocular telescopes (52 of 64), teleloupes (52 of 64), pocket magnifiers (55 of 64), reading glasses (17 of 64), indoor filters for glare control (28 of 64), outdoor filters for glare control (55 of 64), reading stands (53 of 64), lamps for illumination control (48 of 64), and low-vision or talking watches (49 of 64).

OUTCOMES

Table 2 shows the comparison of the mean changes in primary outcome (visual reading ability) and secondary visual ability outcomes (visual information processing, mobility, visual motor skills, and overall ability) in logits from baseline to 4 months for the treatment and control groups, with the last baseline observation carried forward. Compared with the control group, patients in the treatment group reported improvement in visual reading ability (difference, 2.43; 95% confidence interval [CI], 2.07-2.77), visual mobility (difference, 0.84; 95% CI, 0.58-1.10), visual information processing (difference, 1.38; 95% CI, 1.15-1.62), visual motor skills (difference, 1.51; 95% CI, 1.22-1.80), and overall visual ability (difference, 1.63; 95% CI, 1.40-1.86). All statistical comparisons yielded probabilities $<.001$. Within-group improvement was found in all functional domains in the treatment group. Patients in the control group experienced a small but significant decrease in all visual functions except visual motor skills from baseline to the 4-month follow-up. These outcomes were not altered after adjusting for covariates. The effect size of differences between the treatment and control groups for visual reading ability, visual mobility, visual information processing, visual motor skills, and overall visual ability were 2.51, 1.14, 2.03, 1.82, and 2.51, respectively.

The as-treated analysis included 55 patients in the treatment group and 62 patients in the control group with 4-month outcome data. Compared with the control group, the mean changes from baseline to 4 months in the treatment group were 2.40 vs –0.37 for visual reading ability (difference, 2.77; 95% CI, 2.47-3.06); 0.66 vs –0.27 for visual mobility (difference, 0.93; 95% CI, 0.66-1.20); 1.38 vs –0.20 for visual information processing (difference, 1.58; 95% CI, 1.36-1.80); 1.71 vs –0.04 for visual motor skills (difference, 1.75; 95% CI, 1.48-2.02); and 1.67 vs –0.20 for overall visual ability (difference, 1.86; 95% CI, 1.67-2.05). All comparisons yield probabilities $<.001$. Effect size based on the as-treated analyses was 3.5 for visual reading ability, 1.2 for visual mobility, 2.6 for visual information processing, 2.4 for visual motor skills, and 3.6 for overall visual ability. As expected, the effect sizes were larger than those calculated when the last (baseline) observation was carried forward.

Figure 2 displays the differences in mean 4-month changes in the 4 visual ability domains and overall visual ability within subgroups of patients defined by age,

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baseline distance visual acuity, and presence or absence of vision fluctuations. The differences in all subgroups met our criterion for statistical significance ($P<.05$) in all visual function domains. As compared with the control group, treated patients 80 years or younger exhibited greater improvement and patients who reported fluctuations in vision exhibited less improvement in visual function after rehabilitation.

QUALITY OF LIFE

Table 3 presents the changes in quality-of-life scores from baseline to 4 months of follow-up for the treatment and control groups. There was a trend toward improvement in physical role limitations ($P=.08$) and mental health ($P=.07$) on the SF-36. There were no significant differences in mean changes in other SF-36 subscales between the treatment group and control group. No significant difference was observed in mean change in CES-D score between the 2 groups.

ADVERSE EVENTS

No adverse events or serious adverse events were judged to be related to the study.

COMMENT

This randomized clinical trial demonstrated that, using a practice model advocated by most professional societies,[12-14] outpatient low-vision rehabilitation services provided for veterans who are mostly white, male, and currently covered by Medicare[16] significantly improved the functional visual ability of patients moderately and severely impaired by low vision compared with patients in a similarly impaired wait-list control group who received no low-vision services and who lost functional ability over the same 4-month interval. Patients with low vision in the treatment group demonstrated a 2.06-logit improvement in visual reading ability after completion of the intervention while patients in the control group exhibited a 0.37-logit loss in visual reading ability over the same 4-month interval between the baseline and follow-up assessments. Significant improvements in functional ability for mobility, visual information processing, visual motor skills, and overall ability also were seen in the treatment group; small losses in these functions were observed in the control group (Table 2).

An earlier outcome study of patients at a VA blind rehabilitation center compared measures of overall visual ability at 3 months postintervention with repeated measures at 12 months postintervention and demonstrated that the improvements in visual ability observed at 3 months were significantly diminished when observed again at 12 months.[43] Similarly, in a recent functional outcome study, de Boer et al[25] observed that patients lost visual ability over a 1-year follow-up period after completion of low-vision rehabilitation. Thus, the magnitude of a treatment effect may depend on the length of the follow-up interval. A key issue in LOVIT and in future studies of low-vision rehabilitation will be the persistence of a treatment effect. Although not prespecified, a 1-year follow-up of the LOVIT patients was added to the study protocol to compare the magnitude of the treatment effect at 4 months and 1 year. These results will be reported in a future article.

The magnitude of the LOVIT treatment effect is comparable with that observed in an outcome study of a similar sample of patients treated at a VA inpatient blind reha-

Table 3. Mean Changes in QOL Scores From Baseline to 4 Months[a]

QOL Measures	Mean (SD) Treatment Group[b] (n=55)	Mean (SD) Control Group[b] (n=61)	*P* Value: Treatment vs Control
SF-36[37] scales			
Physical functioning			
Baseline	46.4 (11.2)	46.6 (8.9)	.41
Change from baseline to 4 mo	−1.2 (3.9)	−1.9 (5.6)	
Physical role limitations			
Baseline	43.9 (8.7)	42.6 (8.5)	.08
Change from baseline to 4 mo	0.4 (7.6)	−2.2 (7.8)	
Bodily pain			
Baseline	47.7 (11.3)	48.7 (12.2)	.83
Change from baseline to 4 mo	0.3 (11.3)	0.8 (13.0)	
Vitality			
Baseline	50.1 (10.2)	47.3 (10.5)	.43
Change from baseline to 4 mo	0.1 (8.2)	−1.2 (9.1)	
Social functioning			
Baseline	49.3 (10.2)	50.8 (9.9)	.25
Change from baseline to 4 mo	1.1 (8.6)	−0.9 (9.6)	
Emotional role limitations			
Baseline	53.0 (6.2)	51.5 (8.6)	.14
Change from baseline to 4 mo	0.1 (6.2)	2.0 (8.0)	
Mental health			
Baseline	53.9 (8.0)	53.2 (7.9)	.07
Change from baseline to 4 mo	0.4 (7.9)	−2.0 (6.0)	
General health			
Baseline	44.5 (10.6)	44.3 (10.8)	>.99
Change from baseline to 4 mo	−1.1 (9.4)	−1.1 (8.4)	
PCS (physical component)			
Baseline	42.8 (9.4)	43.1 (9.3)	.44
Change from baseline to 4 mo	−0.7 (5.9)	−1.6 (6.9)	
MCS (mental component)			
Baseline	54.9 (8.5)	53.7 (8.1)	.60
Change from baseline to 4 mo	0.8 (7.3)	0.1 (7.0)	
CES-D[38]			
Baseline	8.3 (7.1)	9.2 (8.8)	.47
Change from baseline to 4 mo	−0.2 (5.9)	0.7 (7.2)	

Abbreviations: CES-D, Center for Epidemiologic Studies Depression Scale; QOL, quality of life; SF-36, Short Form–36.

[a] Changes in self-reported health status measured with the Short Form-36 and Symptoms of Depression measured with the Center for Epidemiologic Studies Depression Scale from baseline to 4 months are compared in the treatment and control groups.

[b] The patients who completed the 4-month follow-up visit.

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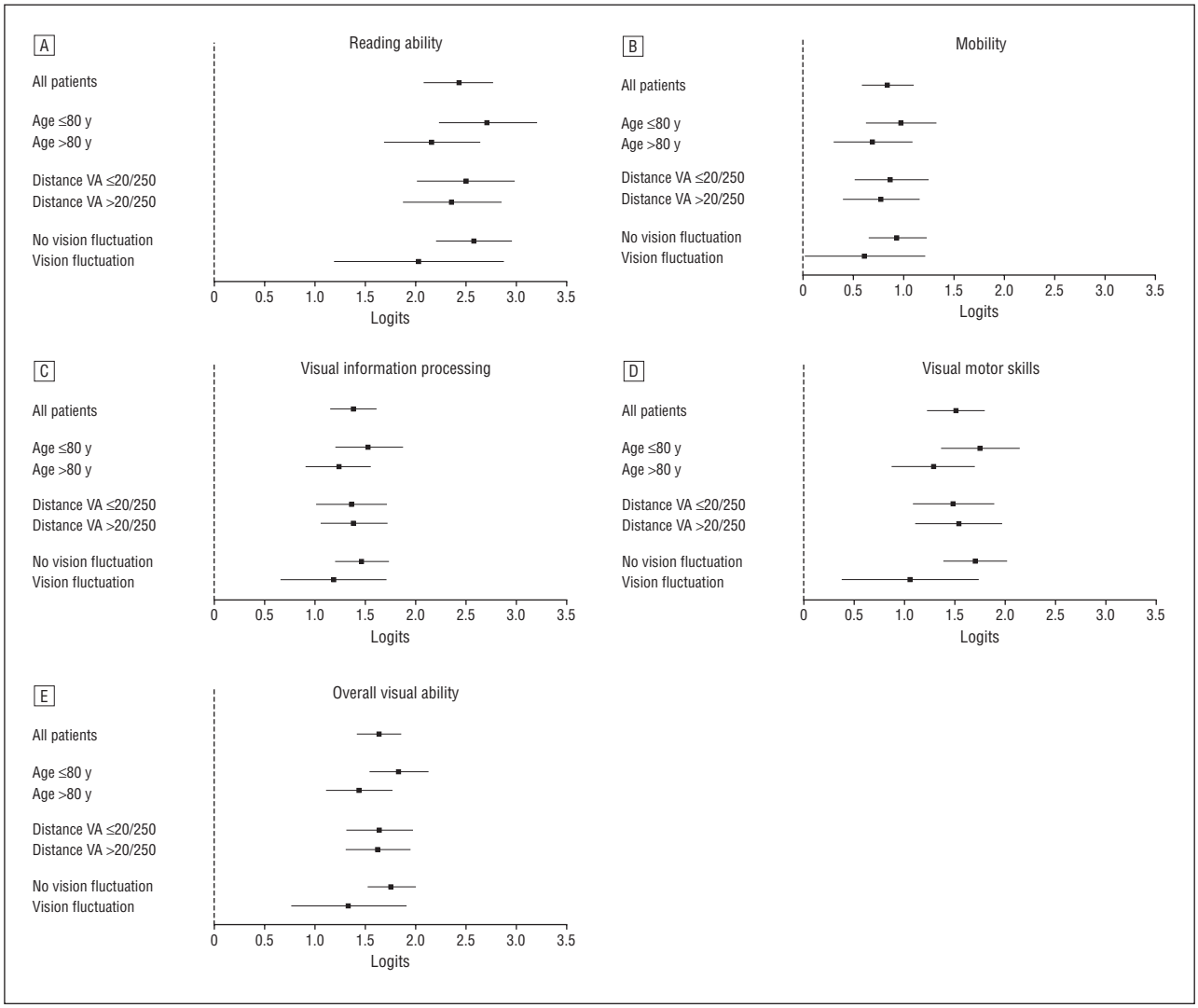

Figure 2. Differences in mean changes in reading ability (A), mobility (B), visual information processing (C), visual motor skills (D), and overall visual ability (E) for all patients and within subgroups of patients defined by age, baseline distance visual acuity, and presence or absence of visual fluctuations. The data points represent differences in mean 4-month changes between the treatment and control groups. All patients: n=126; age ≤ 80 y: n=61; age > 80 y: n=65; distance VA ≤ 20/250: n=66; distance VA > 20/250: n=60; no vision fluctuation: n=96; vision fluctuation: n=30. VA indicates visual acuity.

bilitation center.[24] The LOVIT treatment effect for overall visual ability, normalized to the standard deviation, was larger than the treatment effect observed in that study (2.51 for LOVIT vs 2.09 for the earlier inpatient study) and 8 times larger than the average treatment effect observed in previous outcome studies of outpatient low-vision rehabilitation services. Potential explanations for the differences from previous studies may be due to differences in measurement resolution of the various self-report instruments and scoring algorithms used, differences in visual impairment severity, diagnoses or other patient traits for the various samples of patients with low vision, differences between studies in treatment protocols, and differences between studies in the acquisition of devices by patients and/or the types of low-vision devices dispensed. The last possibility is particularly noteworthy because all patients in the LOVIT treatment group and all veterans who receive services at the VA inpatient blind rehabilitation centers obtained prescribed assistive devices, including a closed-circuit television magnifier, free of charge. Typically, there was little or no public health care funding to provide low-vision devices for patients in the earlier private sector studies; patients had to bear most, if not all, of the device costs. As was observed for other discretionary health care costs in the RAND Health Insurance Experiment,[44,45] the coverage of low-vision device costs may affect the acquisition rate of prescribed devices and therefore affect treatment outcomes.

LOVIT had many strengths in addition to the multicenter randomized controlled trial design including a well-defined treatment protocol that was consistently administered at both clinical sites, inclusion of validated questionnaires to assess outcomes and health status, and the participation of a data coordinating center and data monitoring committee for scientific oversight, quality assurance, and monitoring.

The LOVIT treatment group received a low-vision examination, counseling, and provision of prescribed low-vision devices, 6 weekly therapy sessions, and assigned homework. The therapy manual and homework exercises

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are posted on the VA Optometry and Johns Hopkins Low Vision Consensus Project Web sites (http://www.va.gov/optometry/ and http://www.lowvisionproject.org). These materials can be used in clinical service delivery or included in future research studies. The low-vision devices that were prescribed were the same at both sites and all participants obtained low-vision devices to enhance their remaining vision at no charge.

Previous outcome studies and randomized clinical trials on low-vision rehabilitation tested the effectiveness of standard low-vision clinic services (ie, limited to recommending devices and instructing patients how to use them) or comprehensive low-vision rehabilitation services (ie, standard services plus home evaluation, activities of daily living training, and psychosocial counseling). Usual care or usual care plus an intervention of interest were provided rather than following a strict protocol for all aspects of intervention in both cases. None of the previous studies reported the intensity or duration of therapy sessions. Average visual acuity in the better eye (median Snellen or mean logarithm of the minimal angle of resolution) ranged across studies from 20/66 to 20/200. LOVIT recruited patients with moderate and severe vision loss from macular diseases with visual acuity less than 20/100 and better than 20/500.

Outcomes in previous studies have been evaluated by many different criteria. Some studies have measured speed and/or accuracy of surrogate tasks in the clinic (ie, reading speed, ability to use devices to perform activities, ability to read a certain print size, or visual acuity with prescribed devices) to determine the outcomes of rehabilitation.[46] For individuals with chronic conditions, where a cure is not possible, outcomes must address effects that people experience and care about such as changes in ability to function at home and in the community after rehabilitation.[47] The primary and secondary outcome measures in LOVIT are patient self-reports of community functioning. Clinical measures of performance, such as MNREAD and the therapists' ratings of patients' skills using their remaining vision and low-vision devices, were only administered in the treatment group. They are used in LOVIT to explain the outcomes. Results will be reported in future articles.

The LOVIT intervention is focused on improving reading ability. Thus, the primary outcome measure for the trial is the improvement in patients' perception of their visual reading ability. Patient perception of difficulty is a critical component of low-vision device use (eg, reading newsprint). Low-vision practitioners anecdotally report that patients may exhibit improved performance with low-vision reading devices during clinical evaluations and training but then abandon the device when it comes to everyday activities. An earlier outcome study of patients with low vision at VA blind rehabilitation centers reported abandonment rates ranging from 14% for handheld telescopes to 32% for spectacle microscopes.[48,49] Therefore, a well-validated patient-reported outcome as a measure of effectiveness was chosen over a performance-based measure of efficacy.

The choice of patient-reported outcome measure is important to the interpretation of the results. Most visual functioning questionnaires (VFQs) measure the same visual ability variable, just with different levels of accuracy and precision.[50,51] But, the National Eye Institute VFQ, and perhaps other VFQs, exhibits differential item functioning, ie, only a subset of the items in the VFQ are sensitive to change, so change measures are diluted by the unresponsive items.[21,52] The VA LV VFQ was carefully designed and validated to avoid the measurement distortion effects of differential item functioning.[24] Physical and mental health domains, as measured by the SF-36, are independent of visual ability, as measured by VFQs.[53] Although we do not expect the LOVIT intervention to alter physical and mental health, comorbidities could act as effect modifiers. Therefore, the CES-D and SF-36 were used in LOVIT to describe the characteristics and comorbidities in the patients who participated in the trial. The exploration of the effects of these domains on the primary outcome will be the subject of a future report.

The LOVIT treatment protocol had multiple components: education and counseling, correction of refractive error, eccentric viewing training, provision of low-vision assistive devices and instruction in their use, homework, and home environment evaluation and modifications. We do not know which of these components, or combination of components, is primarily responsible for the large treatment effect observed. Furthermore, each participant assigned to the treatment group received extensive personal attention that was not given to subjects in the control group. Since there was no sham treatment for the control group or social contact control group, we cannot rule out a Hawthorne effect. An earlier randomized controlled trial on the effectiveness of problem-solving therapy for a similar sample of patients with low vision who received no low-vision rehabilitation services showed only small but nevertheless significant improvements in function (effect size of 0.08).[17]

Although the LOVIT protocol addresses rehabilitation goals shared by most patients with low vision, there are important differences between VA and private sector programs that must be considered before generalizing the LOVIT results. The US military veteran population is mostly male whereas the low-vision population served by the private sector is primarily female.[10] Veterans Affairs health care policies differ significantly from those of Medicare, which is the primary source of coverage for health care costs for many patients with low vision in the private sector. Current Medicare laws and policy grant Part B coverage of evaluation and management services provided to patients with low vision by optometrists and ophthalmologists and for rehabilitation therapy provided to patients with low vision in the clinic, patient's home, or patient's community by occupational therapists (with medical necessity based on visual impairment *ICD-9-CM* codes).[54] Medicare requires occupational therapists to provide services under a physician-approved plan of care and have the physician evaluate progress, authorize continued services every 30 days, and complete the planned care within 90 days. Services provided by certified low-vision therapists are not covered by Medicare outside of the ongoing Medicare Low Vision Rehabilitation Demonstration Project in 4 states and 2 urban areas.[15] Medicare does not cover the costs of low-

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vision devices or the costs of eyeglasses for patients with low vision. In contrast, the VA covers the costs of low-vision devices, including expensive electronic magnification devices and eyeglasses, for patients participating in VA rehabilitation programs.

In conclusion, to our knowledge, LOVIT is the first multicenter randomized controlled trial to provide compelling evidence of the effectiveness of low-vision rehabilitation. LOVIT evaluated an outpatient low-vision program for patients with macular diseases developed to model low-vision services provided by the VA inpatient blind rehabilitation centers. The observed magnitude of the treatment effect of the LOVIT outpatient program is comparable with that observed in an earlier study of a VA inpatient blind rehabilitation program. Although future studies are required to determine which components of the program are necessary and sufficient to obtain the large treatment effect reported, the LOVIT treatment protocol agrees with the low-vision practice recommendations of professional societies[12-14] and is covered by Medicare Part B.[16] Thus, based on the large effect sizes observed for a variety of functional domains, the investigators conclude that at least 10 hours of outpatient low-vision therapy, including a home visit, is justified for patients moderately and severely impaired by low vision. Assigned homework that is reviewed by the instructor and patient is recommended to encourage patients to practice everyday tasks using low-vision devices and techniques. Furthermore, because of the small decline in functional ability over time observed in the waitlisted control group, the investigators recommend that low-vision rehabilitation services be offered as early as possible after visual impairment is diagnosed.

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