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# Treatment of Uncorrected Refractive Error Improves Vision-Specific Quality of Life

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**OBJECTIVES:** To evaluate the benefit of eyeglasses and magnifiers in elderly patients with uncorrected refractive errors.

**DESIGN:** A single-center, randomized, prospective, controlled trial (September 2001 to August 2003).

SETTING: Los Angeles County, California.

**PARTICIPANTS:** One hundred thirty-one communitydwelling persons aged 65 and older who had habitual distance visual acuity of 20/32 or worse and whose distant visual acuity, near visual acuity, or both could be improved with eyeglasses, a magnifier, or both by two lines of acuity or more.

**INTERVENTION:** Sixty-six were randomized to receive a prescription and voucher for free eyeglasses, a magnifier, or both immediately, and 65 were randomized to receive a prescription and voucher after the 3-month follow-up visit (the control group).

**MEASUREMENTS:** Primary outcome was vision-specific functioning as measured using the 25-item National Eye Institute—Visual Functioning Questionnaire (NEI-VFQ). Secondary outcomes were distance and near visual acuity and overall functioning as measured using the Rosow-Breslau function questionnaire.

**RESULTS:** In the intention-to-treat analysis of 3-month follow-up data, participants who received the eyeglasses prescription and voucher immediately had greater improvement in NEI-VFQ composite scores than the control group (P < .01). They also had greater improvement in perceptions of their general vision (P < .01), distance visual acuity (P = .03), near visual acuity (P = .04), and mental health (P = .02).

**CONCLUSION:** Correction of uncorrected refractive error, one of the leading causes of visual impairment in older

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people, improved the vision-specific quality of life of community-dwelling older persons. J Am Geriatr Soc 54:883– 890, 2006.

Key words: vision-specific quality of life; uncorrected refractive error; eyeglasses; magnifiers

Incorrected refractive error of any magnitude affects 25% to 54% of adults aged 40 to 80 in the United States.<sup>1-6</sup> The functional and societal effect of uncorrected refractive error can be difficult to estimate, because in the prevailing culture, much of the responsibility and costs associated with updating prescriptions for eyeglasses are left to the individual. Nevertheless, uncorrected refractive error is the most common cause of visual impairment in older individuals,<sup>7</sup> and visual impairment is one of the leading causes of physical decline with aging.<sup>8-10</sup> If visual impairment is left untreated, there is a greater risk of functional decline, social isolation, falls, hip fractures, accidents, and mortality.<sup>8,11–14</sup> Given the high costs of visual impairment to society and the individual, it is surprising that there is such a high prevalence of uncorrected refractive error, because it can be so easily remedied with new eyeglasses and magnifiers. One potential factor is that there have been no randomized, controlled trials evaluating the effect of the correction of refractive error or use of magnifiers in persons with uncorrected refractive error and near-normal vision or moderate-low vision, although there has been a nonrandomized clinical trial evaluating the effect of low-vision services on vision-specific and overall quality of life.<sup>15</sup> A randomized clinical trial was designed to estimate the effect of this noninvasive therapy on vision-targeted quality of life and overall independence with activities of daily living (ADLs) in community-dwelling older persons.

#### **METHODS**

#### Study Design

One hundred thirty-one community-dwelling individuals aged 65 and older with habitual binocular visual acuity of 20/32 or worse whose distance or near visual acuity could be improved by at least two lines of acuity (10 letters)

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were recruited. Participants were randomized to receive an immediate (intervention group) or 3-month-delayed (control group) prescription and a voucher for free eyeglasses, magnifiers, or both. Eligibility criteria required participants to have a fixed residence for the following 3 months, to speak and understand English, to have a phone or another way that the research team could schedule and confirm their home visit, to ambulate independently with a cane or walker, to have a Mini-Mental State Examination (MMSE) score of 23 or more, and to be capable of providing written informed consent. Institutional review board approval was obtained at the University of California at Los Angeles (UCLA).

To identify potentially eligible subjects, screening examinations were held in community locations in Los Angeles County. All subjects who participated in the screening examination gave verbal consent to do so. The screening examination consisted of a brief questionnaire to ascertain demographic characteristics, including socioeconomic status; measurement of binocular distance visual acuity on a standard illuminated logarithmic acuity chart (Early Treatment Diabetic Retinopathy Study (ETDRS) chart "R" from Precision Vision, LaSalle, IL); and assessment of cognitive function measured using the clock drawing test.

Three months after screening examinations started, to increase the ability to recruit participants for the trial, the screening visual acuity was relaxed from a visual acuity of 20/40 or worse to 20/32 or worse, the lower age limit was reduced from 75 to 65, and the minimum MMSE score was decreased from 23 to 20. A visual acuity ranging from 20/30 to 20/60 is considered to be near-normal vision, which means that individuals are able to function fairly normally but have no visual reserve, whereas visual acuity ranging from 20/80 to 20/160 is defined as moderate-low vision, and individuals with this acuity level may need rehabilitation.<sup>16</sup>

Subjects who met the eligibility criteria, who had habitual binocular visual acuity of 20/32 or worse, and who gave written informed consent underwent an eligibility examination. This examination sought to determine whether their binocular distance or near visual acuity could be improved by two lines of visual acuity or more (at least 10 letters) with new eyeglasses or magnifiers. Participants whose near visual acuity did not improve 10 letters or more with a reading lens used magnifiers. During the examination, it was also determined whether their MMSE score was 20 or more, indicating acceptable cognitive status,<sup>17</sup> and whether they had a score less than 6 on the Geriatric Depression Scale short form (GDS), indicating the absence of depression.<sup>18</sup> Individuals with scores of 6 or greater on the GDS were referred to a psychiatrist or psychologist in the area and were ineligible to be randomized. In addition, all subjects who underwent the eligibility examination completed the Self-Administered Comorbidity Questionnaire<sup>19</sup> and had a complete dilated ocular examination by an ophthalmologist. Subjects with an ocular disease that needed treatment were referred to an ophthalmologist in the surrounding area and were ineligible for randomization.

The Peppercenter Data Management Core generated the allocation sequence for randomization, which was in blocks of four (2 interventions, 2 controls). Randomization was stratified within groups defined by presence or absence of age-related macular degeneration (AMD) to ensure balance between groups of this condition. The randomization sequence was concealed until treatment groups were assigned. Once participants were eligible to be randomized, they were handed a sealed numbered envelope that corresponded to the random allocation sequence. This envelope included the voucher for free eye glasses or a letter informing the participant that they would be receiving the voucher at the study's conclusion. The study coordinator immediately gave a prescription for eyeglasses, and a magnifier, if needed, to participants who were randomized to eyeglasses or magnifiers; the correction needed by the participant was specified on the voucher. These participants were encouraged to obtain their new glasses as soon as possible. Participants who were randomized to eyeglasses, magnifiers, or both after the 3-month follow-up visit were informed that they would receive the prescription and voucher for the free eyeglasses and magnifiers at the study's conclusion. Participants were followed up in their homes 3 months after randomization.

#### Outcome Measures

The primary outcome for this clinical trial was change in vision-specific functioning as measured using the 25-item National Eye Institute—Visual Functioning Questionnaire (NEI-VFQ). The NEI-VFQ is a vision-targeted health-related quality-of-life questionnaire that uses a standardized focus group method to develop measures of functioning in three areas: general health and vision, difficulty with visual activities, and emotional responses to vision problems.<sup>20,21</sup> The NEI-VFQ subscale test-retest reliability as measured using intraclass correlations was between 0.68 and 0.91 for all scales. The correlations of the near and distance vision scales with binocular ETDRS visual acuity were 0.71 and 0.67, respectively.<sup>20</sup>

The analysis was supplemented with measures of visual acuity and overall functioning. Binocular distance vision at the screening and home examinations were measured using a portable standard illuminated logarithm of minimum angle of resolution (logMAR) chart (Precision Vision). Binocular near visual acuity was measured using the Lighthouse Near Visual Acuity Test "Modified ETDRS" charts 1 and 2 at an illumination of 60 foot candles. Bestcorrected binocular distance visual acuity before randomization was measured on the BVAT PC logMAR chart (Medtronics Solan, Jacksonville, FL). At the follow-up examination, neither examiners nor participants were masked to treatment group.

To assess overall functioning, the Rosow-Breslau function questionnaire,<sup>22</sup> which consists of three questions that produce six response categories, was used. From these six response categories, a Guttman scale of reported functional health is created. The items include questions on ability to walk a quarter of a mile, to climb up and down at least two steps, and to perform heavy chores (e.g., yard work, washing windows).

#### Sample Size and Statistical Analyses

It was calculated that a sample size of 63 participants per group completing the study would allow the null hypothesis of no difference in the NEI-VFQ composite score between treatment arms to be rejected with 80% power in a two-sided test at  $\alpha = 0.05$  if the true difference was 10 points or greater (an effect size of 0.5 standard deviations).<sup>21</sup> Study outcomes were analyzed according to original treatment assignment (intention to treat). To assess the effectiveness of the randomization, all demographic variables and baseline values of outcome variables (NEI-VFQ scores, near and distance visual acuity) were first compared between the two treatment groups. Three-month outcome variables and changes between baseline and 3-month outcomes were compared between the two treatment groups using t tests and multiple linear regression models adjusted for the corresponding baseline measurements, age, and AMD. Categorical variables were compared using Fisher exact or chi-square tests. Correlations were calculated between baseline values, follow-up values, and changes in the outcome variables. Because randomization was stratified by the presence of AMD, an exploratory subgroup analysis was performed comparing treatments between participants with and without AMD. Exploratory subgroup analyses were also performed comparing treatments of participants who received only magnifiers (n = 38) and with those of participants who received eyeglasses/magnifiers (n = 93). All analyses were performed using SAS statistical software version 8.2 (SAS Institute, Inc., Cary, NC). The UCLA Claude D. Pepper Older Americans Independence Center assisted with the study design; with data collection, tracking, entry, management, analysis, and interpretation; and with the decision to submit the manuscript.

#### RESULTS

Between September 2001 and August 2003, 1,309 subjects were screened at 48 different locations, including senior community centers, senior apartment buildings, senior assisted living facilities, health fairs, and Native American Cultural Centers in Los Angeles County. Of the 1,309 subjects, 1,178 (90%) were ineligible to participate in the randomized trial. The majority of these subjects (63%) had habitual binocular distance visual acuity better than 20/32, 129 (11%) were younger than 65, 88 (7%) had less than 10 letters (2 lines of acuity) of improvement of their distance or near visual acuity, and 70 (6%) refused to have the eligibility examination, leaving 131 subjects who were enrolled in the randomized intervention trial after providing informed consent. Subjects who were ineligible to participate were younger on average and more likely to be Hispanic than those who were eligible (Table 1).

Of the 131 participants, 20 (15%) did not have the follow-up examination, leaving 111 available for 3-month follow-up analyses. Of these who did not provide 3-month follow-up data, six were nonresponsive to phone calls and certified letters, eight were unable to schedule or complete a follow-up examination within the 3-month window, three moved, and three refused follow-up. There were no statistically significant demographic differences in those who did not have follow-up examination and those who did in the control or intervention group.

A majority of trial participants were Caucasian, a majority were female, and a plurality were widowed (Table 2). Baseline characteristics were similar between the treatment groups. The main reasons for visual acuity worse than 20/40 were AMD and cataracts. Trial participants had a

Table 1. Demographic	Characteristics	of Eligible	and Inel-
igible Subjects			

Characteristic	Eligible (n = 131)	Ineligible (n = 1,178)	P-value*
Age, mean $\pm$ standard deviation	$80.4 \pm 8.2$	$\textbf{77.1} \pm \textbf{9.4}$	<.01
Male, n (%)	37 (28)	353 (30)	.66
Race, n (%)			.02
White	83 (63)	683 (58)	
Black	24 (18)	203 (17)	
Asian	10 (8)	93 (8)	
Hispanic	4 (3)	139 (12)	
Other	10 (8)	52 (4)	
Marital status, n (%)			.29
Married	29 (22)	310 (27)	
Divorced	20 (15)	206 (18)	
Widowed	65 (50)	561 (48)	
Single	16 (12)	94 (8)	
Education, n (%)			.33
<high school<="" td=""><td>20 (15)</td><td>251 (22)</td><td></td></high>	20 (15)	251 (22)	
High school	47 (36)	380 (33)	
Some college	37 (28)	282 (24)	
≥College	27 (21)	251 (22)	
Income, \$, n (%)			.52
<10,000	55 (46)	483 (45)	
10,000–16,999	28 (24)	290 (27)	
17,000-22,999	15 (13)	129 (12)	
23,000–29,999	14 (12)	83 (8)	
≥30,000	7 (6)	85 (8)	

\* *P*-values from Student *t* test for age and chi-square tests for comparing difference between two groups.

habitual binocular distance and near visual acuity of 32 and 46.5 letters, respectively, which corresponds to an overall visual acuity slightly better than 20/63. They were less symptomatic than low-vision patients, who had a visual acuity of 20/250 in the better eye, and as symptomatic as patients with AMD in the NEI-VFQ test sample.<sup>20</sup> The type of vision correction needed by participants in both treatment arms was similar (Table 3).

#### Intention-to-Treat Analysis

Eight participants (14.8%) in the glasses-immediately group did not obtain new glasses before the 3-month follow-up, whereas two participants (3.5%) who received a prescription and voucher at the 3-month follow-up had already obtained new glasses. These subjects were analyzed in the group to which they were randomized.

At 3 months after randomization, participants who had received prescriptions for eyeglasses/magnifiers and vouchers experienced better self-reported general vision, near visual acuity, distance visual acuity, mental health, and composite scores as reported on the NEI-VFQ than participants who received the prescription and voucher after the 3-month follow-up visit (Table 4). In addition, there was a trend for participants who received prescriptions for eyeglasses, magnifiers, and vouchers immediately to experience better overall functioning on the Rosow-Breslau scale.

	Glasses Now (n = 66)		Glasses Later (n = 65)		
Characteristic	With F/U (n = 54)	Without F/U (n = 12)	With F/U (n = 57)	Without F/U (n = 8)	<i>P</i> -value*
Age, mean $\pm$ standard deviation	$\textbf{79.3} \pm \textbf{8.1}$	$\textbf{86.3} \pm \textbf{8.9}$	$80.1 \pm 8.0$	$81.1 \pm 7.3$	.58
Male, n (%)	14 (26)	4 (33)	17 (30)	2 (25)	.65
Race, n (%)					.94
White	35 (65)	7 (58)	37 (65)	4 (50)	
Black	9 (17)	4 (33)	9 (16)	2 (25)	
Asian	5 (9)	0 (0)	5 (9)	0 (0)	
Hispanic	2 (4)	0 (0)	1 (2)	1 (13)	
Other	3 (6)	1 (8)	5 (9)	1 (13)	
Marital status, n (%)					.59
Married	12 (23)	1 (8)	16 (28)	0 (0)	
Divorced	9 (17)	0 (0)	7 (12)	4 (50)	
Widowed	27 (51)	9 (75)	25 (44)	4 (50)	
Single	5 (9)	2 (17)	9 (16)	0 (0)	
Education, n (%)					.94
<high school<="" td=""><td>9 (17)</td><td>3 (25)</td><td>8 (14)</td><td>0 (0)</td><td></td></high>	9 (17)	3 (25)	8 (14)	0 (0)	
High school	17 (31)	8 (67)	20 (35)	2 (25)	
Some college	16 (30)	1 (8)	18 (31)	2 (25)	
≥College	12 (22)	0 (0)	11 (20)	4 (50)	
Income, \$, n (%)					.90
<10,000	24 (50)	8 (80)	22 (41)	1 (14)	
10,000–16,999	10 (21)	1 (10)	12 (22)	5 (71)	
17,000–22,999	6 (13)	0 (0)	8 (15)	1 (14)	
23,000–29,999	5 (10)	1 (10)	8 (15)	0 (0)	
≤30,000	3 (6)	0 (0)	4 (7)	0 (0)	
Presence of age-related macular degeneration	16 (30)	5 (42)	25 (44)	2 (25)	.12

\* T test for age and chi-square tests for comparing difference between subjects in two treatment groups who had follow-up.

Changes in binocular distance and near visual acuity and GDS scores were similar between the two groups.

When the analyses were adjusted for the corresponding baseline measurement, age, and presence of AMD, participants who received only glasses (and not a magnifier) immediately had better general, distance, and near visual acuity; mental health; and composite scores on the NEI-VFQ, than participants who received a prescription and voucher 3 months later (Table 5). Distance and near visual acuity of participants randomized to receive glasses only at baseline improved by 4.7 and 7.1 letters more, respectively, than that of the control group, whereas distance and near visual acuity of those with magnifiers only worsened by 2.3 and 2.2 letters, respectively.

#### **Additional Analyses**

In subgroup analyses, of those with AMD, scores of the immediate treatment group improved, whereas those of the delayed treatment group worsened (NEI-VFQ composite score: 4.3 vs -2.0, P = .04; general health score: 10.9 vs -3.0, P = .03; general visual acuity score: 8.8 vs -2.4, P = .04). Of those without AMD, scores of the immediate treatment group improved, whereas those of the delayed treatment group worsened (NEI-VFQ composite score: 7.5 vs -0.2, P < .01; general visual acuity score: 11.1 vs -1.9, P < .01; distance visual acuity score: 11.2 vs 0.8, P = .01; and mental health score: 11.6 vs 0.2, P = .05.

Because magnifiers are a method of treating low vision, the results were analyzed without the inclusion of the 38

	Glasses N	ow (n = 66)	Glasses Later ( $n = 65$ )		
Type of Vision Correction	Baseline $(n = 66)$	With F/U (n = 54)	Baseline (n = 65)	With F/U (n = 57)	<i>P</i> -value*
Eye glasses only Eye glasses and magnifiers Magnifiers only	35 (53) 12 (18) 19 (29)	31 (57) 8 (15) 15 (28)	36 (55) 10 (15) 19 (30)	33 (58) 9 (16) 15 (26)	.98

 Table 3. Type of Vision Correction Needed

\* Chi-square tests for comparing difference in type of vision correction between subjects in two treatment groups who had follow-up. F/U = 3-month follow-up.

		With Glasses Now (n = 54)	Wit	h Glasses Later (n = 57)	
Characteristic	n (Mean $\pm$ Standard Deviation)				<i>P</i> -value <sup>‡</sup>
25-Item National Eye Institute-Visual Function	ing Questi	onnaire (range 0–100)			
General health	54	$(4.2 \pm 18.0)$	57	$(-0.4 \pm 17.4)$	.17
General vision	54	$(10.4 \pm 18.1)$	57	$(-2.1 \pm 14.0)$	<.01
Near vision	54	$(7.6 \pm 19.1)$	57	$(0.4 \pm 17.4)$	.04
Distance vision	54	$(3.3 \pm 23.2)$	56	$(-6.3 \pm 22.7)$	.03
Driving	32	$(0.0\pm20.8)$	26	$(0.5 \pm 12.0)$	.92
Peripheral vision	51	$(7.8\pm28.9)$	56	$(-0.5 \pm 24.5)$	.11
Color vision	54	$(3.7\pm17.1)$	55	$(-0.9 \pm 18.0)$	.17
Ocular pain	54	$(6.9 \pm 21.3)$	57	$(2.9\pm22.7)$	.33
Vision-specific					
Role limitation	52	$(10.6 \pm 26.6)$	57	$(3.7\pm23.9)$	.16
Dependency	52	$(0.9\pm22.6)$	57	$(-2.4 \pm 25.3)$	.48
Social functioning	53	$(4.5\pm21.0)$	57	$(-0.9 \pm 19.6)$	.17
Mental health	54	$(11.2 \pm 25.3)$	57	$(0.4 \pm 24.2)$	.02
25-item composite score	54	$(6.5\pm9.3)$	57	$(-0.8 \pm 10.8)$	<.01
Geriatric Depression Scale (range 0–15)	54	(–0.3 ± 1.9)	57	$(-0.1 \pm 2.1)$	.58
Rosow-Breslau (range 0–5) Visual acuity	45	$(0.07\pm1.3)$	50	$(-0.4\pm1.4)$	.07
Distance (range 0–70 letters)	54	$(5.5 \pm 10.0)$	57	$(3.9 \pm 10.4)$	.41
Near (range 0–75 letters)	54	(6.1 ± 13.3)	57	$(2.2 \pm 11.4)$	.10

#### Table 4. Change in Primary and Secondary Outcomes from Baseline to Follow-Up by Treatment Group

<sup>‡</sup>Student *t* test for comparing difference in changes between two treatment groups.

subjects who relied only on magnifiers to improve their near visual acuity. At 3 months after randomization, participants who received prescriptions for eyeglasses or for eyeglasses and magnifiers experienced better general visual acuity (11.8 vs -2.4, P < .01), near visual acuity (9.2 vs -0.2, P = .02), distance visual acuity (7.2 vs -5.6, P = .01), mental health (14.4 vs 0.7, P = .01), and NEI-VFQ composite scores (7.8 vs -0.7, P < .01) than participants who received the prescriptions and vouchers at the 3-month follow-up. In addition, they tended to have better general health (5.8 vs -0.6, P = .08) and fewer role limitations (10.8 vs 1.2, P = .08) due to vision problems, and their binocular near visual acuity was better at follow-up (8.6 vs 2.9, P = .05).

#### DISCUSSION

This randomized trial of individuals aged 65 and older with uncorrected refractive error demonstrated clear benefits of eyeglasses and magnifiers on vision-specific quality of life. Significant benefits in perceptions of general, distance, and near visual acuity and mental health/well-being due to vision were found in the intervention group, despite the fact that there were improvements in measured binocular habitual distance and near visual acuity in both groups.

The prevalence of uncorrected refractive error of two lines of acuity or more is 6.4% to 12% in the United States and Australia.<sup>3–6,23</sup> Prior population-based studies<sup>8,24–28</sup> have shown an association between visual impairment and overall functioning, but these studies have not usually distinguished uncorrected refractive error from less-reversible causes of poorer visual acuity such as AMD. In the Proyecto VER study,<sup>27</sup> uncorrected refractive error was associated with decrements on nine of the subscales of the NEI-VFQ. These decrements were similar to those seen with age-related cataracts. Visual impairment in older persons is associated with functional decline, carrying with it the risk of more-frequent placements in nursing homes or other assisted living situations,<sup>28</sup> with corresponding consequences for individual quality of life and healthcare costs.

Improvement in vision-targeted functioning after correction of uncorrected refractive error has rarely been documented in published studies. One example was a study at a low-vision referral clinic,<sup>15</sup> where correction of uncorrected refractive error and provision of low-vision aids were associated with subjective improvements in vision-related functioning. Although the current results have similarities to those found in this nonrandomized trial of 156 consecutive patients who were contacted by telephone before and 3 months after an examination in a low-vision clinic, the current study population's average distance visual acuity of 20/63 is considered to be near-normal vision, whereas the median distance visual acuity of 20/200 in the low-vision population is defined as low vision.<sup>16</sup> In the lowvision study population, of whom 47% (73/156) had uncorrected refractive error and 13.5% (21/156) were given a change in their eyeglass prescription only, the scores of four subscales of the NEI-VFQ (general, near, and distance visual acuity; peripheral vision) improved, whereas none of the subscales of the 36-item Short Form changed significantly after the provision of low-vision services. In the current study, 100% of participants had uncorrected refractive error, and 54.2% were given a prescription for new eyeglasses only.

Outcome	Treatment Effect	95% Confidence Interval		P-value			
25-Item National Eye Institute-Visual Functioning Questionnaire (range 0–100)							
General health							
Glasses later	Reference						
Glasses immediately only	5.54	- 2.30	13.38	.16			
Magnifier immediately only	0.70	- 9.27	10.68	.89			
Glasses and magnifier immediately	7.44	-5.63	20.51	.26			
General vision							
Glasses later	Reference						
Glasses immediately only	11.60	4.93	18.27	.001			
Magnifier immediately only	5.74	-2.90	14.37	.19			
Glasses and magnifier immediately	17.78	6.56	29.00	.002			
Near vision							
Glasses later	Reference						
Glasses immediately only	5.35	- 2.37	13.07	.17			
Magnifier immediately only	0.46	- 9.46	10.38	.93			
Glasses and magnifier immediately	11.99	- 0.93	24.91	.07			
Distance vision	11.00	0.00	21.01				
Glasses later	Reference						
Glasses immediately only	9.29	0.66	17.92	.04			
Magnifier immediately only	- 3.46	- 14.47	7.55	.54			
Glasses and magnifier immediately	16.00	1.67	30.34	.03			
Driving	10.00	1.07	00.04	.00			
Glasses later	Reference						
Glasses immediately only	2.38	- 8.42	13.19	.66			
Magnifier immediately only	- 9.89	- 23.00	3.21	.00			
Glasses and magnifier immediately	- 9.89 - 6.64	- 23.59	10.32	.14			
Peripheral vision	- 0.04	- 23.39	10.52	.44			
Glasses later	Deference						
	Reference	E 1E	15 60	20			
Glasses immediately only	5.27	- 5.15 - 6.02	15.69 21.20	.32 .27			
Magnifier immediately only	7.59		-				
Glasses and magnifier immediately	7.09	- 10.93	25.11	.44			
Color vision	D (						
Glasses later	Reference	0.40		10			
Glasses immediately only	4.48	-2.19	11.14	.19			
Magnifier immediately only	- 1.27	- 9.82	7.27	.77			
Glasses and magnifier immediately	4.51	-6.49	15.51	.42			
Ocular pain							
Glasses later	Reference						
Glasses immediately only	1.54	-6.97	10.04	.72			
Magnifier immediately only	4.44	- 6.26	15.13	.41			
Glasses and magnifier immediately	3.43	- 10.49	17.35	.63			
Vision-Specific							
Role limitation							
Glasses later	Reference						
Glasses immediately only	8.81	- 2.47	20.10	.12			
Magnifier immediately only	3.43	- 10.63	17.50	.63			
Glasses and magnifier immediately	-0.77	- 19.01	17.47	.93			
Dependency							
Glasses later	Reference						
Glasses immediately only	5.37	- 5.22	15.96	.32			
Magnifier immediately only	- 3.65	- 16.76	9.46	.58			
Glasses and magnifier immediately	9.30	- 7.67	26.27	.28			
Social functioning							
Glasses later	Reference						
Glasses immediately only	6.51	- 1.21	14.23	.10			
Magnifier immediately only	- 2.35	- 12.48	7.78	.65			
Glasses and magnifier immediately	1.28	- 11.46	14.03	.84			

# Table 5. Adjusted Treatment Effects on Follow-Up Outcome Measurements: Results from Multiple Linear Regression Models

Table 5.	(Contd.)
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Outcome	Treatment Effect	95% Confidence Interval		P-value
Mental health				
Glasses later	Reference			
Glasses immediately only	9.89	- 0.19	19.97	.05
Magnifier immediately only	- 0.66	- 13.62	12.31	.92
Glasses and magnifier immediately	24.62	7.89	41.35	.004
25-item composite score				
Glasses later	Reference			
Glasses immediately only	7.07	2.97	11.18	.001
Magnifier immediately only	2.61	- 2.69	7.90	.33
Glasses and magnifier immediately	9.46	2.63	16.29	.007
Geriatric Depression Scale score (range 0-	15)			
Glasses later	Reference			
Glasses immediately only	0.11	- 0.71	0.93	.79
Magnifier immediately only	0.17	-0.88	1.21	.75
Glasses and magnifier immediately	- 0.66	- 2.01	0.69	.34
Rosow-Breslau (range 0–5)				
Glasses later	Reference			
Glasses immediately only	0.48	- 0.10	1.06	.10
Magnifier immediately only	0.15	- 0.62	0.92	.70
Glasses and magnifier immediately	- 0.46	- 1.58	0.65	.41
Visual acuity (range 0–70 letters)				
Distance				
Glasses later	Reference			
Glasses immediately only	4.66	0.84	8.49	.02
Magnifier immediately only	- 2.25	- 7.08	2.59	.36
Glasses and magnifier immediately	- 5.02	- 11.30	1.27	.12
Near				
Glasses later	Reference			
Glasses immediately only	7.07	2.20	11.94	.005
Magnifier immediately only	- 2.17	- 8.30	3.96	.48
Glasses and magnifier immediately	5.81	- 2.35	13.96	.16

Note: Adjusted for the corresponding baseline measurement, age, and age-related macular degeneration.

In another study evaluating the effect of rehabilitation on patients at two low-vision clinics of the Department of Veterans Affairs,<sup>29</sup> improvements in visual acuity were independent of the decrease in difficulty with tasks that were easier after rehabilitation: difficulty reading ordinary print, difficulty reading small print, difficulty figuring out bills, and difficulty going to the movies. Participants from the two clinics had average best-corrected visual acuity of 20/63 and 20/100.

This study had several limitations. It was difficult to find participants with uncorrected refractive error. Of those who were screened, 62% had current binocular visual acuity better than 20/32, and only 10% had decreased visual acuity that could be improved by two or more lines of acuity ( $\geq$ 10 letters). The prevalence of uncorrected refractive error of 10% that was found is similar to that reported in other population-based studies in the United States and Australia.<sup>3-6,22</sup>

Another limitation was that distance and near visual acuity did not improve as much as expected in the intervention group, despite the fact that one of the enrollment requirements was an improvement in visual acuity of 10 letters or more with eye glasses or magnifiers. In a study evaluating the reproducibility of repeated measurements of visual acuity in screening and clinical settings, measurements of visual acuity in the same setting are identical in only 75.4% of eyes and are within one line of acuity (5 letters) in 92.1%.<sup>30</sup> In the current study, the intervention group's distance and near visual acuity changed by more than one line of acuity (5.5 and 6.1 letters, respectively), whereas the change in the control's group visual acuity was within one line of acuity. Across both groups, approximately 9% of participants did not comply with their treatment assignment. It is especially surprising that 14.8% of participants randomized to obtain new glasses immediately did not obtain new glasses before the 3-month follow-up visit, despite the fact that the eyeglasses were free. This lack of compliance may have affected the ability to detect a larger acuity change at follow-up in the glasses-immediately group. In addition, the improvement in vision-targeted quality of life and preservation of independence in ADLs in the intervention group may be because new glasses give better visual functioning on average in ways that are not accounted for by visual acuity, such as, they are less scratched, not bent, or better looking and so are more likely to be worn.

Because participants were not masked to the intervention, there is the possibility that a Hawthorne effect or learning effect led to improvement in the measured, followup visual acuity in the control group. In addition, because participants were selected based on poor visual acuity, the gains in the control group could represent regression to the mean for their true values. This improvement in visual acuity did not prevent us from detecting a difference in the vision-specific quality of life between the two groups from being detected. This points out the importance of having a control group; presumably, masking of participants to treatment group would have helped even more.

Despite these limitations, this trial is the first randomized trial comparing immediate correction of uncorrected refractive error with delayed correction. The findings provide support for the intuitive conclusion that correction of uncorrected refractive error is beneficial to communitydwelling individuals and documents that this is the case not only for low vision but also for near-normal vision. Based on these findings, older persons and their providers should be made aware of the prevalence of uncorrected refractive error and the potential benefits in terms of perceptions of vision-targeted quality of life and preservation of independence in ADLs.

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#### REFERENCES

 Refractive Error. San Francisco, CA: American Academy of Ophthalmology, 2001.

- Klein R, Klein BE, Lee KE. Changes in visual acuity in a population. The Beaver Dam Eye Study. Ophthalmology 1996;103:1169–1178.
- Tielsch JM, Sommer A, Witt K et al. Blindness and visual impairment in an American urban population. The Baltimore Eye Survey [see comments]. Arch Ophthalmol 1990;108:286–290.
- Klein BE, Klein R, Lee KE et al. Associations of performance-based and selfreported measures of visual function. The Beaver Dam Eye Study. Ophthalmic Epidemiol 1999;6:49–60.
- Attebo K, Mitchell P, Smith W. Visual acuity and the causes of visual loss in Australia. The Blue Mountains Eye Study. Ophthalmology 1996;103:357– 364.
- Munoz B, West SK, Rodriguez J et al. Blindness, visual impairment and the problem of uncorrected refractive error in a Mexican-American population: Proyecto VER. Invest Ophthalmol Vis Sci 2002;43:608–614.
- Rowe S, MacLean C, Shekelle PG. Preventing visual loss from chronic eye disease in primary care. JAMA 2004;291:1487–1496.
- Reuben DB, Damesyn M, Moore AA et al. The prognostic value of sensory impairment in older persons. J Am Geriatr Soc 1999;47:930–935.
- Branch LG, Horowitz A, Carr C. The implications for everyday life of incident self-reported visual decline among people over age 65 living in the community. Gerontologist 1989;29:359–365.
- 10. Keller BK, Morton JL, Thomas VS et al. The effect of visual and hearing impairments on functional status. J Am Geriatr Soc 1999;47:1319–1325.
- West SK, Munoz B, Rubin GS et al. Function and visual impairment in a population-based study of older adults. The SEE project. Salisbury Eye Evaluation. Invest Ophthalmol Vis Sci 1999;38:72–82.
- 12. Cummings SR, Nevitt MC, Browner WS et al. Risk factors for hip fractures in white women. N Engl J Med 1995;332:767–773.
- Klein BE, Klein R, Lee KE et al. Performance-based and self-assessed measures of visual function as related to history of falls, hip fractures, and measured gait time. Ophthalmology 1998;105:160–164.
- Thompson JR, Gibson JM, Jagger C. The association between visual impairment and mortality in elderly people. Age Ageing 1989;18:83–88.
- Scott IU, Smiddy WE, Schiffman J et al. Quality of life of low-vision patients and the impact of low-vision services. Am J Ophthalmol 1999;128:54–62.
- Folstein MF. The Mini-Mental State Examination. In: Crook T, Ferris S, Bartus R, eds. Assessment in Geriatric Psychopharmacology. New Canaan, CT: Mark Powley, 1983, pp 50–51.
- Fletcher DC, Colenbrander A. Introducing rehabilitation. In: Fletcher DC, ed. Low Vision Rehabilitation: Caring for the Whole Person. San Francisco, CA: American Academy of Ophthalmology, 1999, pp 1–9.
- Sheikh JI, Yesavage JA, Brooks JO 3rd et al. Proposed factor structure of the Geriatric Depression Scale. Int Psychogeriatr 1991;3:23–28.
- Sangha O, Stucki G, Liang MH et al. The Self-Administered Comorbidity Questionnaire: A new method to assess comorbidity for clinical and health services research. Arthritis Rheum 2003;49:156–163.
- Mangione CM, Lee PP, Pitts J et al. Psychometric properties of the National Eye Institute Visual Function Questionnaire (NEI-VFQ). Arch Ophthalmol 1998;116:1496–1504.
- Mangione CM, Lee PP, Gutierrez PR et al. Development of the 25-item National Eye Institute Visual Function Questionnaire. Arch Ophthalmol 2001;119:1050–1058.
- 22. Rosow I, Breslau N. A Guttman health scale for the aged. J Gerontol 1966;21: 556–559.
- Foran S, Wang JJ, Mitchell P. Causes of incident visual impairment. Arch Ophthalmol 2002;120:613–619.
- 24. Salive ME, Guralnik J, Glynn RJ et al. Association of visual impairment with mobility and physical function. J Am Geriatr Soc 1994;42:287–292.
- Wang JJ, Mitchell P, Smith W et al. Factors associated with use of community support services in an older Australian population. Aust N Z J Public Health 1999;23:147–153.
- Wang JJ, Mitchell P, Smith W et al. Impact of visual impairment on use of community support services by elderly persons. The Blue Mountains Eye Study. Invest Ophthalmol Vis Sci 1999;40:12–19.
- Broman AT, Munoz B, Rodriguez J et al. The impact of visual impairment and eye disease on vision-related quality of life in a Mexican-American population. Proyecto VER. Invest Ophthal Vis Sci 2002;43:3393–3398.
- Tielsch JM, Javitt JC, Coleman A et al. The prevalence of blindness and visual impairment among nursing home residents in Baltimore. N Engl J Med 1995; 332:1205–1209.
- Stelmack JA, Stelmack TR, Massof RW. Measuring low-vision rehabilitation outcomes with the NEI VFQ-25. Invest Ophthal Visual Sci 2002;43:2859– 2868.
- Hawkins BS. Reliability of visual acuity measurements and screening under field conditions. Ophthalmic Epidemiol 1995;2:99–106.