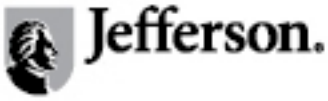

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Purpose. To compare the efficacy of behavioral activation (BA) plus low vision rehabilitation with an occupational therapist (OT-LVR) with supportive therapy (ST) on visual function in patients with age-related macular degeneration (AMD).

Methods. Single-masked, attention-controlled, randomized clinical trial with AMD patients with subsyndromal depressive symptoms ($n = 188$). All subjects had two outpatient low vision rehabilitation optometry visits, then were randomized to in-home BA + OT-LVR or ST. Behavioral activation is a structured behavioral treatment aiming to increase adaptive behaviors and achieve valued goals. Supportive therapy is a nondirective, psychological treatment that provides emotional support and controls for attention. Functional vision was assessed with the activity inventory (AI) in which participants rate the difficulty level of goals and corresponding tasks. Participants were assessed at baseline and 4 months.

Results. Improvements in functional vision measures were seen in both the BA + OT-LVR and ST groups at the goal level ($d = 0.71$; $d = 0.56$ respectively). At the task level, BA + OT-LVR patients showed more improvement in reading, inside-the-home tasks and outside-the-home tasks, when compared to ST patients. The greatest effects were seen in the BA + OT-LVR group in subjects with a visual acuity $\geq$20/70 ($d = 0.360$ reading; $d = 0.500$ inside the home; $d = 0.468$ outside the home).

Conclusions. Based on the trends of the AI data, we suggest that BA + OT-LVR services, provided by an OT in the patient's home following conventional low vision optometry services, are more effective than conventional optometric low vision services alone for those with mild visual impairment. (ClinicalTrials.gov number, NCT00769015.)

Keywords: visual function, depression, age-related macular degeneration, low vision rehabilitation

Age-related macular degeneration (AMD) is a degenerative eye disease that leads to progressive central vision loss, which can severely affect an individual's ability to socialize, read, drive, and live independently.[1–4] An estimated 10% to 30% of visually impaired patients with AMD develop clinically significant depression.[5–6] Depression in AMD is associated with a decline in visual function and greater levels of disability, medical costs, and mortality rates.[7–11] Clinical research studies demonstrate that outpatient low vision rehabilitation services can improve functional ability.[12–19] A recently completed clinical trial, the Low Vision Depression Prevention Trial in Age-Related Macular Degeneration (VITAL), demonstrated that behavioral activation (BA) plus low vision rehabilitation delivered by an occupational therapist (OT-LVR) in the patients' home reduced the incidence of severe depression in high-risk AMD patients with low vision.[20]

Participants in both the active treatment and control groups (a placebo condition to control for attention) in the VITAL study received conventional low vision evaluation and low vision optometry services provided in an outpatient optometric clinic prior to randomization. Only the active treatment group was given BA + OT-LVR. The supportive therapy (ST) control group received an equal amount of in-home attention from a social worker or counselor, but did not receive any additional low vision rehabilitation services or advice. Because patients' functional ability was measured in the VITAL study by administering the activity inventory (AI), an adaptive self-report rating scale instrument, before the initial low vision evaluation by the optometrist and again 4 months later after their respective in-home interventions (masked to treatment assignment), we have the opportunity to evaluate the effectiveness of adding in-home BA + LVR to optometric low vision services, with a control for the potential response-biasing effects on

functional outcome measures of attention from an empathetic and supportive therapist.

The purpose of the present study is to evaluate the functional outcomes of visually impaired AMD patients using secondary functional outcome measures from the VITAL study. We are interested in learning if in-home BA + LVR provided by an occupational therapist added to conventional optometric low vision services are more effective in improving the patients' functional ability than are conventional optometric low vision services plus in-home supportive therapy provided as an attention control.

Methods

Subjects

Eligibility criteria were: (1) age >65 years; (2) bilateral AMD (either neovascular disease or geographic atrophy); (3) best eye corrected visual acuity <20/70; (4) >5 anti-VEGF injections if the better eye had neovascular disease (or no injections in past 3 months); (5) moderate difficulty performing a valued activity; and (6) subthreshold depressive symptoms, defined as a Patient Health Questionnaire-9 (PHQ-9) score of >5[21] or depressed mood or anhedonia several days per week. We excluded patients with cognitive deficits (assessed by an abbreviated version of the Mini Mental State Exam),[22] impending anti-VEGF treatment, diagnosis of major depression, dysthymia, or other axis I psychiatric disorder as defined by *Diagnostic and Statistical Manual of Mental Disorders*, 4th edition (DSM-IV), or other ophthalmologic disease.

Medical charts were reviewed to identify those who met eligibility criteria. Recruitment letters were mailed and followed by telephone calls by a research assistant to ascertain study interest and to screen for eligibility (depressive symptoms, cognitive functioning, and difficulty with valued activities). A research nurse then visited participants in their homes to obtain informed consent and to administer the baseline assessment. All procedures were approved by the Institutional Review Board at Thomas Jefferson University and adhered to the tenets of the Declaration of Helsinki.

Procedures

After the baseline assessment, all subjects had two visits with a study optometrist before randomization into the two treatment groups. The optometrists provided their usual low vision evaluation and patient training in the clinic. Up to $350 was provided to each subject toward the purchase of low vision devices as recommended by the low vision optometrist.

Subjects were randomized using a random numbers table and fixed scheme with a 1:1 allocation ratio. Assignment to each treatment group was stratified by severity of vision loss. The BA + OT-LVR treatment arm received services by an OT to address depression and functional limitations from vision loss. This intervention involved six in-home 1-hour sessions over a period of 8 weeks with one of five study OTs. The behavioral activation component of the intervention emphasized links between action, mood, and mastery and promoted self-efficacy and social connection. The low vision rehabilitation component of the intervention followed an occupational therapy plan of care based on the evaluation results and patient goals. The occupational therapists had regular communication with the treating optometrists to update them on subjects' progress with their goals. The supportive therapy group received services from social workers or counselors who provided emotional support. These services involved six in-home 1-hour sessions with one of three study social workers/counselors over a period of 8 weeks. Supportive therapy, which emphasized personal expression about vision loss and disability, was designed to control for nonspecific effects of attention. Aside from the initial LVR services received from the optometrist, no additional in-home LVR services were provided to the subjects in the ST group.

Relevant to the present study, self-reported functional ability was measured using the AI at baseline and 4 months after treatment.[23–26] Also included were measures of depression using the PHQ-9.[21,27,28] Vision impairment measures consisted of distance and near visual acuity (VA), contrast sensitivity, and size and locations of central scotomas. The primary outcome measure in the trial was diagnosis of depression as defined in the VITAL study report.[20] Here we analyze the functional outcome measures for the two treatment groups from patient responses to the AI.

Measures

The activity inventory and PHQ-9 were administered by a nurse in the patient's home at baseline prior to the optometrist's low vision evaluation and services and again 4 months later (±5 days) after completion of BA + OT-LVR or ST provided in the home. The activity inventory consists of 50 goal-level activities (e.g., manage personal finances, prepare daily meals) and an item bank of 460 tasks (e.g., specific cognitive and motor activities such as read bills, write checks, measure ingredients, and pour liquids), nested under the 50 goals. The subject was asked to rate the importance of performing each goal activity without depending on another person (not important, slightly important, moderately important, very important). If the goal was rated not important, the interviewer moved on to the next goal. If the goal was rated at least slightly important, the interviewer asked the subject to rate the difficulty of performing the goal activity without depending on another person (not difficult, slightly difficult, moderately difficult, very difficult, or impossible). If the goal was rated not difficult, the interviewer moved on to the next goal. If the goal was rated at least slightly difficult, the subject was asked to rate the difficulty of the tasks nested under that goal (using the same rating categories used for the goal, or the subject could respond that the task is not applicable to the way they perform the goal activity).[23]

The research nurse then verified depression eligibility by administering the PHQ-9, a self-report questionnaire designed to provide information on specific disorders using the criteria from the DSM, at the baseline assessment. Rasch analysis of the patients' responses to the PHQ-9 was used in the present study to estimate a continuous interval-scaled "depression severity" variable.[27,28]

Analyses

Rasch analysis, employing the Andrich rating scale model,[29,30] was used to estimate four different visual ability measures, one from subjects' difficulty ratings of AI goals and three from subjects' difficulty ratings of subsets of AI tasks (reading, inside-the-home and outside-the-home tasks). Previous studies have shown that two independent visual function factors underlie visual ability measures estimated from difficulty ratings of activities, one related to visual acuity and the other related to loss of peripheral vision and/or scotomas.[31] Visual ability estimated from goal difficulty ratings fall close to the principal axis in the two-factor space (i.e., loading approximately equally on the two factors). Person measures estimated from different combinations of tasks fall in the same two-factor space, but plot at different positions depending on the ratio of overall

Table 1. Activity Inventory Effect Size (Cohen's *d*) Categorized at the Goal and Task Levels

	Effect Size at 4 Months			
Treatment Group	**Goal**	**Reading**	**Inside-the-Home**	**Outside-the-Home**
BA + OT-LVR*	0.713 ($P < 0.001$)	0.328 ($P = 0.002$)	0.634 ($P < 0.001$)	0.555 ($P < 0.001$)
ST†	0.559 ($P < 0.001$)	0.168 ($P = 0.14$)	0.312 ($P = 0.012$)	0.19 ($P = 0.15$)
Group Effect‡	0.10 ($P = 0.20$)	0.17 ($P = 0.073$)	0.21 ($P = 0.030$)	0.27 ($P = 0.013$)

* Within group comparison of BA + OT-LVR change scores (4-month follow-up person measure minus baseline person measure); The values of *P* are for 1-tailed paired *t*-tests comparing baseline person measures to 4-month follow-up person measures estimated from difficulty ratings of AI goals and the three sets of AI tasks (reading, inside-the-home, and outside-the-home tasks).

† Within group comparison of ST change scores (4-month follow-up person measure minus baseline person measure); The values of *P* are for 1-tailed paired *t*-tests comparing baseline person measures to 4-month follow-up person measures estimated from difficulty ratings of AI goals and the three sets of AI tasks (reading, inside-the-home, and outside-the-home tasks).

‡ Between group comparison of change scores (4-month follow-up person measure minus baseline person measure); The values of *P* are for 1-tailed unpaired *t*-tests comparing BA + OT-LVR change scores to ST change scores.

dependence on the acuity-related factor to overall dependence on the scotoma-related factor of the sample of tasks. Because rehabilitation is expected to increase functional reserve (i.e., difference between the person's visual ability [person measure] and the visual ability required to perform the activity described by the item [item measure]), AI item measures and response category thresholds were anchored to baseline values estimated previously from the responses of 3200 low vision patients.[32] Anchoring item measures and response category thresholds forces all changes in functional reserve, whether increases in the person's ability (e.g., from refractive error correction) or person-specific decreases in the required ability for an item (e.g., from the use of a low vision aid), to manifest as changes in the estimated person measures.[33–34] Items that were rated as "not difficult" at baseline were filtered out for both baseline and follow-up person measure estimates, since there is no room for improvement and they would not be included as rehabilitation goals in the patient's plan of care.[15] We report 1-tail *t*-tests comparing within group differences pre- and posttreatment and between group differences, BA + OT-LVR versus ST. One-tail *t*-test results are reported because we are interested in whether or not patients improved in visual function and not reporting statistics from those who report getting worse from progression of AMD.

A minimum clinically important difference (MCID) for each of the four visual ability measures was estimated for each subject by subtracting the baseline person measure from the 4-month follow-up person measure and dividing by 1.96 times the corresponding standard error of the baseline person measure.[15] The minimum clinically important difference is considered a clinical endpoint, so if MCID >1 for a subject (i.e., $P < 0.05$), then the effect of intervention on the measure for that subject is given a score of 1, otherwise it is scored as 0. Rasch analysis also was performed on the PHQ-9 responses to estimate continuous interval–scaled measures of a depression-related psychologic state variable ("depression severity").[27,28] One-tailed *t*-tests were used to compare the depression severity distribution of patients exhibiting a significant MCID to the distribution of patients who did not have a significant MCID.

Results

Complete demographics and clinical characteristics of the 188 participating patients (BA + OT-LVR group: $n = 96$; ST group: $n = 92$) are described in the VITAL study report.[20] To summarize, mean patient age was 84 years (range, 67–97 years) and 70.2% were women. Best-corrected binocular visual acuity ranged from 0.01 to 2.2 logMAR (20/20–20/3170) with a median of 0.64 logMAR (20/87). Nineteen subjects (10.1%) dropped out of the study (BA + OT-LVR group: 7; ST group: 12), seven additional subjects did not complete the AI. These 26 subjects did not differ in their distribution of PHQ-9 scores.

Tasks were categorized as either reading, inside-the-home, or outside-the-home activities. As summarized in Table 1 with Cohen's *d*, moderate improvements in functional ability were seen in both the BA + OT-LVR and ST groups at the AI goal level ($d = 0.713$ and $d = 0.559$, respectively). At the AI task level, BA + OT-LVR patients exhibited more improvement in reading, inside-the-home, and outside-the-home activities than did ST patients. When comparing the functional ability outcomes and group effects of BA + OT-LVR to ST, small differences were seen with the functional ability measure based on ratings of inside-the-home and outside-the-home tasks reaching statistical significance.

Median logMAR acuity was 0.51 (~20/70). Participants were divided into two visual acuity groups around the median (≥20/70 and <20/70) to evaluate visual acuity effects on functional ability outcomes. As summarized in Table 2, significant visual acuity effects were seen in both the BA + OT-LVR and ST groups at the AI goal level. The greatest change in visual ability from baseline to follow-up was seen in the BA + OT-LVR group subjects with VA ≥20/70 ($d = 0.571$, $P < 0.001$). This group also exhibited the greatest improvement in functional ability in each of the AI task categories (d = 0.360–0.500). Those BA + OT-LVR subjects with a VA <20/70 exhibited only small effects ($d = 0.046$–0.311). There were no significant improvements in functional ability estimated from task ratings for the ST group for either visual acuity category.

Moderate effects were seen at the goal and task levels when comparing BA + OT-LVR to ST for those patients with a VA ≥20/70. However, none of these effects reached statistical significance after correction for multiple tests. There were small to no group effects of BA + OT-LVR compared to ST for subjects <20/70.

The study VITAL concluded that 11 BA + OT-LVR subjects (12.6%) and 18 ST subjects (23.4%) developed a depressive disorder by the 4-month follow-up (RR, 0.54; $P = 0.036$).[20] The Figure compares changes in depression severity from baseline to 4-month follow-up as change score histograms for the BA + OT-LVR group (black bars) and the ST group (gray bars). Overall, there is no significant difference between the depression severity change score distributions for the BA + OT-LVR and ST groups ($P = 0.402$). The mean change score is −1.06 (SD = 1.15) for the BA + OT-LVR group and −0.88 (SD = 1.45) for the ST group, which indicate reductions in depression severity. However, if we compare the frequency of depression severity increasing (i.e., worse depressed state) at the 4-month follow-up (positive change scores in the highlighted area of the Fig.), 12% of the BA + OT-LVR group

Table 2. Effect Size (Cohen's *d*) Stratified by Visual Impairment Categorized at the Goal and Task Levels

	Outcomes Stratified by Visual Impairment			
Treatment/Visual Impairment Group	**Goal**	**Reading**	**Inside-the-Home**	**Outside-the-Home**
BA + OT-LVR VA 20/70 or better*	0.571 ($P < 0.001$)†	0.360 ($P < 0.001$)†	0.500 ($P < 0.001$)†	0.468 ($P < 0.001$)†
BA + OT-LVR VA worse than 20/70‡	0.313 ($P < 0.001$)†	0.046 ($P = 0.30$)	0.263 ($P = 0.003$)†	0.311 ($P = 0.001$)†
ST VA 20/70 or better§	0.340 ($P = 0.0013$)†	0.072 ($P = 0.26$)	0.255 ($P = 0.023$)	0.113 ($P = 0.21$)
ST VA worse than 20/70||	0.386 ($P < 0.001$)†	0.083 ($P = 0.18$)	0.125 ($P = 0.13$)	0.099 ($P = 0.25$)
Between treatment group effect VA better than 20/70¶	0.382 ($P = 0.01$)	0.404 ($P = 0.009$)	0.321 ($P = 0.027$)	0.459 ($P = 0.007$)
Between treatment group effect VA worse than 20/70#	−0.159 ($P = 0.15$)	−0.045 ($P = 0.39$)	0.139 ($P = 0.18$)	0.170 ($P = 0.15$)
Within group acuity effects BA + OT LVR**	0.460 ($P = 0.002$)†	0.310 ($P = 0.026$)	0.332 ($P = 0.016$)	0.212 ($P = 0.11$)
Within group acuity effects ST††	−0.095 ($P = 0.28$)	−0.062 ($P = 0.36$)	0.119 ($P = 0.24$)	−0.013 ($P = 0.47$)

* Within group comparison of BA + OT-LVR change scores (4-month follow-up person measure minus baseline person measure) for subjects with VA of 20/70 or better (logMAR < 0.55); The *P* values are for 1-tailed paired t-tests comparing baseline person measures to 4-month follow-up person measures.

† Results that reach statistical significance after correction for multiple tests. To get an alpha of 0.05, correction for multiple comparisons is 0.003 for the within group comparisons*–|| and 0.006 for each of the change score group comparisons.¶–††

‡ Within group comparison of BA + OT-LVR change scores (4-month follow-up person measure minus baseline person measure) for subjects with VA worse than 20/70 (logMAR > 0.55). The values of *P* are for 1-tailed paired *t*-tests comparing baseline person measures to 4-month follow-up person measures.

§ Within group comparison of ST change scores (4-month follow-up person measure minus baseline person measure) for subjects with VA of 20/70 or better (logMAR < 0.55). The values of *P* are for 1-tailed paired *t*-tests comparing baseline person measures to 4-month follow-up person measures.

|| Within group comparison of ST change scores (4-month follow-up person measure minus baseline person measure) for subjects with VA worse than 20/70 (logMAR > 0.55). The values of *P* are for 1-tailed paired *t*-tests comparing baseline person measures to 4-month follow-up person measures.

¶ Between group comparison of change scores (4-month follow-up person measure minus baseline person measure) for subjects with VA of 20/70 or better (logMAR < 0.55); The values of *P* are for 1-tailed unpaired t-tests comparing BA + OT-LVR change scores to ST change scores.

Between group comparison of change scores (4-month follow-up person measure minus baseline person measure) for subjects with VA worse than 20/70 (logMAR > 0.55). The values of *P* are for 1-tailed unpaired t-tests comparing BA + OT-LVR change scores to ST change scores.

** Within group comparison of BA + OT-LVR change scores (4-month follow-up person measure minus baseline person measure); The values of *P* are for 1-tailed paired *t*-tests comparing subjects with VA of 20/70 or better to subjects with VA worse than 20/70.

†† Within group comparison of ST change scores (4-month follow-up person measure minus baseline person measure). The values of *P* are for 1-tailed paired *t*-tests comparing subjects with VA of 20/70 or better to subjects with VA worse than 20/70.

had an increase in depressive state at 4 months compared to 26% of the ST ($P = 0.015$).

For the two treatment groups combined, 108 patients had no significant improvement in visual ability estimated from goal difficulty ratings (assigned a MCID score of 0) and 54 patients had a significant improvement (assigned a MCID score of 1). Those subjects who had an MCID score of 1 at the goal level had a mean depression severity change score of −1.26 while those who had a MCID score of 0 had a mean depression severity change score of −0.87 (Table 3). These results indicate

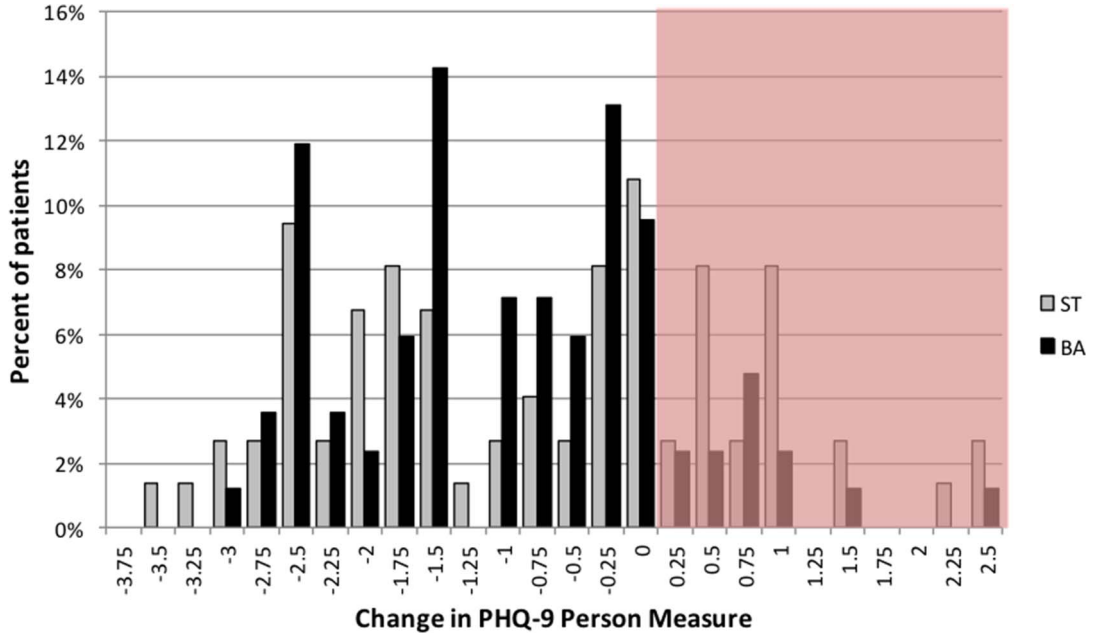

Figure. Person measure PHQ-9 change scores in depression severity from baseline to 4-month follow-up by treatment group. Negative change scores indicate decreases in depressed mood and positive change scores indicate increases in depression severity (*highlighted area*).

Table 3. Change Scores of PHQ-9 Mean Depression Severity

MCID Outcome	Goal	Reading	Inside-the-Home	Outside-the-Home
Mean ΔPHQ-9 MCID 0[1]	−0.87	−0.52	−0.56	−0.52
Mean ΔPHQ-9 MCID 1[2]	−1.26	−0.94	−0.80	−0.85
One-tailed *t*-test	$P = 0.036$	$P = 0.044$	$P = 0.18$	$P = 0.12$

For subjects with binary MCID scores of 0 (no significant improvement in functional ability)[1] and 1 (significant improvement in functional ability)[2] based on visual ability person measures estimated from AI goal responses and the 3 different sets of AI task responses (reading, inside-the-home, and outside-the-home tasks).

that subjects with improvements in functional ability had a greater decrease in depression severity after intervention than those who did not improve in functional ability ($P = 0.036$). Similar results were observed at the task level with only reading tasks exhibiting a statistically significant effect of functional ability improvement on depression severity.

However, despite the significant effect at the goal level, there is no correlation between changes in visual ability and changes in depression severity ($r = -0.0725$, $P = 0.183$).

There was no difference between the two visual acuity groups in depression severity at baseline (mean = −1.37 for acuity <20/70 and mean = −1.34 for acuity ≥20/70, $P = 0.71$). However, after intervention, subjects with VA ≥20/70 had a greater improvement in depression severity (mean change = −0.94) than did those with VA <20/70 (mean change = −0.34; $P = 0.0048$).

Discussion

Improvements in low vision patients' ability to perform daily activities, as measured by the AI, were consistently greater for the BA+OT-LVR group than for the ST group. These results lead us to conclude that functional outcomes are better when occupational therapy is added to standard optometric low vision services than when an equivalent amount of attention only is added. The significant improvements in visual ability we saw in the ST group can be interpreted as concurring with previous studies that concluded that conventional low vision services alone are effective at improving visual function.[12–19] However, those results also could be interpreted as indicative of a response-biasing effect of supportive therapy.

The results of the current study attest specifically to the efficacy of in-home low vision services by an occupational therapist in patients with comorbid depressive symptoms. The added effects of occupational therapy were greater for patients with less severe visual impairments (≥20/70) than they were for patients with more severe visual impairments (<20/70). This result was unexpected because, as shown in the LOVIT study,[13] patients with better visual function at baseline have less room to improve.

We observed that for both the BA+OT-LVR and ST treatment groups, visual ability measures estimated for AI goal difficulty ratings improved by similar large amounts even though the ST group received no LVR beyond the initial optometric low vision services. With the extensive personal attention given to both groups by the therapists, we must consider the possibility that there could be changes in response bias secondary to improvements in mood resulting from attention alone, which could then be responsible for most of the observed effects. This hypothesis is strengthened by the observation of a greater reduction in depression severity for patients in both groups who had significant improvements in functional ability, based on MCID, than for patients who did not have significant improvements. In other words, the severity of depression, rather than or in addition to an actual change in ability, may influence patient's judgments about the difficulty of performing activities, especially when rating the very broadly described AI goals.

Similar effects of MCID were seen when looking at the reading level, meaning there were greater improvements in depression severity for those with significant improvement in reading ability compared to those without significant improvement in reading ability. At the group level, significant improvements in reading ability were seen for BA + OT-LVR patients with VA ≥20/70, but, there were no significant improvements for BA + OT-LVR subjects with VA <20/70. These results suggest that after the initial services provided by the optometrist, there was no additional benefit from in-home OT-LVR for those subjects with poorer vision.

The study design selected for a specific demographic of patients who were considered "at-risk" for developing clinically significant depression. The groups BA + OT-LVR and ST exhibited equal reductions in depression severity after intervention (see Fig.). Although the magnitude of improvement in functional ability did not correlate with the magnitude of reduction in depression severity, the magnitude of reduction in depression severity was significantly greater for patients who had a minimum clinically important difference (MCID of 1) in functional ability at the goal level after intervention. However, we cannot draw conclusions about cause and effect from these observations—elevations of mood from the personal attention both groups received from repeated visits by an OT or social worker/counselor over an 8-week period could cause changes in response bias (i.e., making all activities seem easier), or improvements in functional ability from the optometric low vision services provided to both groups before additional in-home psychotherapy could cause elevations in mood (e.g., secondary to reductions in stress). Alternatively, it can be hypothesized that improved visual function contributed to the decline in depression severity. The VITAL study was not designed to test these alternative hypotheses.

Because both groups received optometric care by a low vision optometrist before randomization, which included initial device evaluation and training, any functional impact from the optometric care given before the home visits would be expected to contribute to both groups' treatment effects. Based on the overall treatment effects seen in the attention control ST group when measured at the task level, it appears that the optometric services and provision of visual assistive equipment without additional OT services only significantly improved functional ability in inside-the-home tasks.

The most likely scenario is that both effects are occurring: the optometric services plus low vision devices may be responsible for improvements in ability and the attention from the therapists may bias the patients' use of the rating scale. When compared to the broad goal level assessments, task descriptions are much more specific with possibly less room for interpretation and response bias.

Because the subjects in the VITAL study were selected to represent low vision patients at high risk for developing severe depression, the effect of depression severity on measures of functional ability may be particularly strong. Besides improvements for both groups in functional ability estimated from

difficulty ratings of daily activities, both groups also showed significant improvements in depression severity estimated from PHQ-9 scores. Recent studies showed that depressed mood, estimated from Rasch analysis of responses to the geriatric depression scale, was a strong predictor in low vision patients of baseline functional ability measured with the AI,[32] but was not associated with changes in functional ability measured after low vision rehabilitation.[15] Given these corroborating observations, the results of the present study have to make us concerned about possible confounding effects of depression severity on the measurement per se of functional ability.

The limitation of the analysis presented here is that the VITAL study was not designed to distinguish the separate contributions to functional ability outcome measures of optometric low vision services, low vision rehabilitation services (plus BA) provided in the patient's home, and the confounding effects of depression severity. A study specifically designed to determine the independent effects of each of these factors on the functional outcomes of low vision rehabilitation is required to properly evaluate the effectiveness of low vision rehabilitation services.

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