Self-management of Age-Related Macular Degeneration and Quality of Life

A Randomized Controlled Trial

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Objective: To assess the effectiveness of an age-related macular degeneration (AMD) self-management program, consisting of health education and enhancement of problem-solving skills, to improve quality of life as shown by measures of mood and function.

Methods: Two hundred thirty-one community-dwelling cognitively intact volunteers (mean age, 80.6 years) with advanced macular degeneration were randomly assigned to a 12-hour self-management program (n=86), a series of 12 hours of tape-recorded health lectures (n=74), or to a waiting list (n=72).

Main Outcome Measures: The primary outcome measure was emotional distress (Profile of Mood States). Secondary outcome measures included function (National Eye Institute Visual Function Questionnaire), social support (Duke Social Support Index), outlook on life (Life Optimism Test–Revised), and self-confidence to handle AMD-specific challenges in daily life (AMD Self-Efficacy Questionnaire). Clinical depression was determined in accord with the Structured Clinical Interview for the Diagnostic and Statistical Manual of Mental Disorders, Axis I, Fourth Edition, Research Version.

Results: The self-management group showed significant improvement in measures of mood and function compared with controls. These changes were significantly greater for the depressed than for the nondepressed subjects. Decreased emotional distress was associated with increased self-efficacy, while improvements in function were associated with increases in self-efficacy and perceived social support.

Conclusions: These findings suggest that the AMD self-management program was an effective intervention to enhance well-being in older persons with poor eyesight due to AMD, particularly in those who were initially depressed.

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Age-related macular degeneration (AMD) remains the leading cause of permanent vision loss in the older population in the industrial world. The burden of distress and disability is enormous for this incurable blinding disease of late life; patients with advanced AMD have been shown to have significant disability and emotional distress similar to or greater than patients with other serious chronic diseases. Age-related macular degeneration affects approximately 5% of the US population overall and 20% of individuals 65 years and older and is now on a trajectory to become an epidemic in aging “baby-boomers” in the 21st century.

Self-management has been found to be effective in improving health outcomes for older persons who have a variety of incurable chronic conditions, including asthma and arthritis, and for adults of varying ages in managing other chronic diseases, such as diabetes, heart disease, insomnia, chronic obstructive pulmonary disease, and cancer. We previously reported a pilot study assessing a structured 6-week self-management course for individuals with AMD. This study demonstrated the value of participation in the self-management program in decreasing emotional distress, especially feelings of depression and anxiety, and increasing self-efficacy and activity. The results of the pilot study suggested that the relationship between participation in the self-management program and improved mood was stronger in the subjects who were initially more distressed. This led us to include assessment for clinical depression using the standardized methods of the Structured Clinical Interview for the Diagnostic and Statistical Manual of Mental Disorders, Axis I, Fourth Edition, Research Version (SCID-...
METHODS

PARTICIPANTS

Participants in this study were recruited through ophthalmologists’ offices, the media, an AMD registry, health fairs, and senior centers. The 231 subjects were enrolled between February 1998 and September 2000. The inclusion criteria were: (1) diagnosis of AMD by an ophthalmologist and confirmed by fundus photographs; (2) visual acuity of 20/60 or worse in the better eye and 20/100 or worse in the other eye with habitual correction (ie, current glasses); (3) no other unstable eye disease or vision loss due to other eye disease; (4) age 60 years or older; (5) adequate hearing, with a hearing aid if necessary, to complete the interview and to respond in normal conversation; (6) physical ability to come to an interview if wheelchair access transportation was provided; (7) no cognitive impairment as assessed by the Orientation-Memory Concentration Test;16 and (8) no current alcohol abuse as assessed by the Short Michigan Alcoholism Screening Test.18

Overall, 252 (72.21%) of the 349 patients screened met the above criteria (Figure). Seventy-one potential subjects (20.34%) were excluded for one of the following reasons: an eye disease was responsible for vision loss (n=20 [5.73%]); other health problems limited mobility (n=5 [1.43%]); and moved out of the area (n=6 [1.72%]). The 26 otherwise eligible volunteers (7.45%) declined participation after learning the study requirements. The study participants and the people who declined participation were similar in demographic and clinical characteristics. In addition, 21 subjects who participated in the baseline portion of the study subsequently declined participation because of personal reasons. They were not significantly different in demographic and clinical characteristics from the participants in the study.

DESIGN AND PROCEDURES

The protocol for this study was approved by the institutional review board and informed consent was obtained. Data used in this study came from baseline and postintervention interviews conducted by a clinical psychologist and trained research assistants using the measures described below. Procedures were in place to keep the treatment assignment of subjects unknown to the interviewer, and subjects did not know the hypotheses of the study. Participants were randomly assigned to 1 of 3 groups: self-management, tape-recorded health education program, or to a waiting list (control group). At the end of the study, the controls were offered participation in the self-management program.

The computer-generated randomization cards were kept in sequentially numbered, individual, sealed envelopes. The randomization key was kept off-site in a double-sealed envelope. On confirmation of eligibility and subject interest, a randomization envelope was opened in the presence of 2 research associates. Each card was signed by 2 researchers, and the randomization result was recorded in a password-protected database.

Trained personnel measured the subjects’ visual acuity with habitual correction, ie, current glasses, in an examination room with standardized lighting conditions. Subjects were encouraged to use their peripheral sight for this examination when appropriate. All data were double entered.

As described previously,13 the 6-week self-management program was held in the eye center conference room, where 8 to 10 participants met weekly for 2-hour sessions led by an experienced professional in public health and behavioral medicine. The sessions incorporated 2 elements: didactic presentations and group problem-solving with guided practice. The didactic component was comprised of brief presentations and formal lectures by professionals in several fields, eg, ophthalmology, rehabilitation, nutrition, exercise physiology, and low vision optometry. In the group problem-solving component, participants were guided through a hierarchy of behavioral challenges to improve problem-solving skills with the support and experience of peers and professionals. The intervention was composed of both cognitive and behavioral components.

Cognitive components included information about the biological processes of AMD, suggestions of ways to maintain or increase activity levels, and hands-on demonstrations and discussions of available visual aids and services. Reevaluation of perceived barriers to independence was encouraged, and positive challenges were provided from peers and group leaders.

Behavioral components included behavioral skills training in communicating with others about visual disability, handling a variety of challenges associated with AMD, and requesting assistance when needed. Modeled after successful psychosocial interventions with chronic disease,12,19 vignettes were presented to the group, covering various problems encountered by people with AMD. In addition, participants presented situations they had faced. Adaptive behaviors were modeled for the participants. A simple exercise program de-
signed for this population was also incorporated into the program.

To control for the provision of educational information, which was the focus of the self-management program, the tape control consisted of a series of 12 hours of audiotapes of health lectures, which had been presented to the lay public, on AMD and healthy aging, to be listened to during a 6-week period. Subjects in the control condition were interviewed again 6 weeks after baseline interviews.

**MEASURES**

**Primary Outcome Measure**

Because the main focus was on mood, we selected the Profile of Mood States (POMS), which is a 65-item, self-report inventory designed to assess emotional distress during the previous week. The POMS was selected for use because it does not include somatic symptoms that might be confounded with physical illness. The participant responds to each item on a 5-point Likert scale, ranging from 0=not at all to 4=extremely. Scores can range from 0 to 232. Higher scores indicate higher levels of emotional distress. The POMS has been validated for use with older populations.

**Secondary Outcome Measures**

In addition to mood, we were interested in the effects of the intervention on everyday functioning. The National Eye Institute Visual Function Questionnaire (NEI-VFQ) is a multifaceted functional measure of health-related quality of life in relation to vision. An overall summary scale of the average of the 12 subscales was used to reduce the chance of type I errors due to multiple comparisons. The total score can range from 0 to 100, where 0 represents the worst possible functioning and 100 the best.

**MEDIATOR VARIABLES**

The following were studied as mediators of the effects of the self-management program on mood and function:

1. Duke Social Support Index 11 item (DSSI-11). The DSSI-11 measures satisfaction with the frequency, content, and quality of support and social interaction with family and friends. Scores range from 0 to open-ended. Higher scores indicate greater perceived social support.

2. Life Orientation Test–Revised (LOT-R). The LOT-R is a 10-item measure with good reliability and validity that assesses optimistic vs pessimistic life outlook. This measure has been shown to capture a personality trait that is conceptualized differently from self-efficacy. Scores range from 0 to 24. Higher scores indicate a more optimistic approach to life.

3. Macular Degeneration Self-Efficacy Questionnaire (AMD-SEQ). As conceptualized in Bandura's social cognitive model, self-efficacy is a person's assessment of his or her abilities and encompasses the degree of certainty and underlying expectations about his or her ability to succeed in a given circumstance. Based on this theory, a self-efficacy questionnaire had been developed to address issues salient to AMD and shown to be reliable. The scale ranges from 1 to 100, with high scores indicating that participants feel very confident they can accomplish the task related to AMD vision loss described in the question. Higher scores indicate greater self-efficacy.

**BASELINE CLASSIFICATION OF DEPRESSION**

To identify subjects with major and minor depressive disorders at baseline, the standardized methodology of portions of the Mood Episodes section (Module A) and the Global Assessment of Function Scale of the SCID-IV was used. The SCID-IV rating of depression in this study population was correlated with baseline POMS scores (Spearman r = 0.39, P = .001).

**MEASURES OF CLINICAL AND DEMOGRAPHIC CHARACTERISTICS**

**Visual Acuity**

Visual acuity was obtained using the Snellen chart. Snellen ratings were then converted to the logMAR scale. Counting fingers, hand motion, light perception, and no light perception were assigned visual acuity values of 20/4000, 20/8000, 20/16000, and 20/32000, respectively.

**Health and Impact Questionnaire**

This instrument obtains a medical history, with questions about current medical conditions, medications, the impact of AMD on life, living arrangements, education, and the principal occupation of the subject and of the main wage earner (spouse) if other than the subject. The principal occupation and education of the main wage earner is used in the Hollingshead Two-Factor Index of Social Position.

**STATISTICAL ANALYSIS**

Statistical analyses were conducted using SPSS for Windows, version 9.0, and Statistica for Windows, version 5.5. Descriptive statistics were used to characterize the sample data at baseline. An unpaired t test and χ² test were used to detect any differences at baseline. The Pearson r was used to determine the relationship at baseline between outcome measures (ie, POMS and NEI-VFQ) and mediator measures (DSSI, LOT-R, and AMD-SEQ). A mixed-design analysis of variance was performed with 2 between-subject factors: treatment (self-management program vs control) and status (depressed vs nondepressed), and 1 within-subject factor: time point (baseline vs 6 week postintervention). Stepwise multiple regression analyses (with a level of significance set at .05 and R² set at 0.05 as the selection criterion) were used to determine any relationship between the changes in scores on emotional distress (POMS) and functioning (NEI-VFQ) tests, and the mediators, ie, the changes in scores on perceived social support (DSSI), dispositional optimism (LOT-R), and self-efficacy (AMD-SEQ). When necessary to satisfy the assumptions of normality and homogeneity of variances, data transformations were performed. Thus, square-root transformations on the POMS and logarithmic transformations on the DSSI were performed. Missing data were deleted case-wise for the subjects who did not complete all of the items of the measures.

The primary hypothesis for the primary outcome measure (ie, POMS) led to the following a priori predictions that were analyzed using planned comparisons: (1) the participants in the self-management group would experience improvement in emotional distress from baseline to postintervention compared with the control group; (2) the depressed participants on the SCID-IV in the self-management group would experience a significant improvement in emotional distress from baseline to postintervention, not only compared with the nondepressed participants, but also compared with the depressed controls. The secondary hypothesis for the secondary outcome measure (ie, NEI-FVQ) and the mediator measures (ie, DSSI, LOT-R, and AMD-SEQ) led to the same a priori predictions.

With the sample size of this study, there was a power of .80 to detect a difference of 0.5 of an SD for moderate effect size between groups on the primary outcome measure, which was the total score on the POMS.
Randomization was successful, resulting at baseline in no differences among the 3 groups on demographic and clinical factors (Table 1). There was no significant difference in the number of depressed subjects in the 3 groups (P > .82). As presented in Table 2, the subjects with and without depression were similar, including being legally blind in the better eye, except that those with depression had somewhat poorer vision (P > .05).

Mixed-design analyses of variance and independent t tests were performed to assess the difference among treatment group (self-management program, tape, waitlist) depression status (depressed vs nondepressed) on the POMS, NEI-VFQ, DDSI, LOT-R, and AMD-SEQ scores from baseline vs postintervention. Change scores between the tape and the control group were not statistically significant (P > .05). These groups were therefore collapsed into 1 control group and compared for analysis with the self-management group.

## PRIMARY ANALYSIS

The self-management program was effective in improving mood, as revealed by the analysis of variance. There was an interaction (P = .02), indicating that participants in the self-management program showed reduced emotional distress on the POMS from baseline to postintervention in comparison with participants in the control group, as predicted (see Table 3 for planned contrasts). There was also a 3-way interaction (P = .001), indicating that the depressed participants in the self-management program reported a reduction in emotional distress compared with the nondepressed and the depressed participants in the control group, as predicted (see Table 4 for planned contrasts).

## SECONDARY ANALYSES

The self-management program was effective in increasing functioning, especially for the participants identified as depressed, as revealed by the analysis of variance. As for the POMS, there was an interaction (P = .04), indicating that participants in the self-management program reported increased functioning on the NEI-VFQ from baseline to postintervention in comparison with participants in the control group, as predicted (see Table 3 for planned contrasts). There was also a 3-way interaction (P = .02), indicating that the depressed patients in the self-management program reported a significant in-
crease in function compared with the nondepressed and the depressed participants of the control group, as predicted (see Table 4 for planned contrasts).

To examine the relationships between the mediator measures (ie, social support [DSSI] optimism [LOT-R] and self-efficacy [AMD-SEQ]) and the outcomes measures (ie, emotional distress [POMS] and function [NEI-VFQ]), Pearson $r$ scores were computed on the baseline data for the sample as a whole. There was a strong association between the level of self-efficacy (AMD-SEQ) and extent of emotional distress (POMS) ($r^2 = -0.50$ [95% CI, −0.61 to −0.38]), and the level of functioning NEI-VFQ) ($r^2 = 0.44$ [95% CI, 0.31-0.55]), showing that subjects who reported less distress and better functioning also were more likely to report that they had greater self-efficacy. For the 2 other mediators, ie, DSSI and LOT-R, the correlations were weak ($−0.28/r^2/0.21$).

Second stepwise multiple regression analyses were performed to examine whether the changes in social support, dispositional optimism, and self-efficacy from baseline to postintervention were related to changes in emotional distress (POMS) and/or changes in functioning.
The study population was composed of 231 cognitively intact, older women and men living in the community who had poor eyesight because of advanced AMD. Approximately 24% met criteria for major or minor depression on the SCID-IV, which is the standard method for identifying depression. This is similar to the proportion of subjects with major or minor depression that we found in our prior cross-sectional analysis of the first 151 subjects at baseline. The present study demonstrates that participants in our AMD self-management program experienced reduced emotional distress and improved functioning when compared with controls. The benefits of the AMD self-management program were demonstrated, particularly in the patients with AMD who were initially depressed. Participants also reported significantly increased self-efficacy on the AMD-SEQ; they felt more confident about their abilities to conduct daily activities despite their condition.

The reduction in emotional distress and improvement in self-efficacy following participation in the self-management program confirmed the findings of our previous pilot study. In the present investigation, we also studied the effect of self-management on disability as measured by the NEI-VFQ. Participants reported less disability after completing the self-management program, as indicated by improvement in carrying out daily life activities more independently and with less difficulty.

To our knowledge, this AMD self-management program was the first of this kind implemented for an older population affected by an ophthalmic condition. The results are consistent with findings of other behavioral medicine interventions. For example, a psychosocial support program resulted in improved mood and perception of pain in patients with breast cancer who were initially more distressed, a psychosocial intervention with melanoma patients led to reduced distress along with improvements in coping, and a self-management program for patients with chronic obstructive pulmonary disease resulted in increased self-efficacy and improved function.

The dynamic of how our AMD self-management program reduced distress and improved function is open to speculation. In addition to standard cognitive behavioral therapy techniques, in the AMD self-management program, the techniques were modified specifically for the older population with poor eyesight due to advanced AMD. For example, we provided information on their disease, including recent AMD research findings that were presented in lay terms without slides, and addressed their specific questions. We challenged them to use their remaining eyesight to maintain their independence and involvement in personally meaningful activities. Demonstrations of low vision aids and devices, almost all of which were available without prescription, focused on instilling participants with the confidence to use them. Also, to promote self-confidence in their remaining abilities, we included 10 minutes of instruction on exercise methods that did not require ambulation or sight (ie, while sitting). Although the associations...
of self-efficacy with mood and function were weak, it is reasonable to speculate that the techniques we used in the self-management program led to the interplay of increased self-efficacy with improvements in mood and function, thereby helping people with AMD to improve their abilities and resources to cope and adapt.

We found that the benefits of reduced distress and improved function in the self-management program were seen particularly in the depressed subjects. It is possible that the POMS had a floor effect, as has been suggested. It is also possible that the patients without depression had already maximized their potential for adaptation to advanced AMD, at least in terms of mood and function, since they reported significantly lower levels of distress and higher levels of function at baseline.

The findings of this study suggest that it may not be necessary to provide self-management for all patients with advanced AMD. However, both depressed and nondepressed subgroups showed increased self-confidence in their abilities to cope with their disease, and the nondepressed patients may have served as role models and contributed to the positive atmosphere of the self-management program.

This study was limited to subjects who had advanced AMD, were cognitively intact, and had no vision loss due to other diseases. It is not known if these findings would apply to all patients with AMD or how the benefits of this intervention fare over time. We plan to address the longer-term effects in future studies.

In summary, this self-management intervention offers an encouraging therapeutic addition to current medical treatments for an ever-growing aging population afflicted with AMD and seems suitable for an eye clinic setting. The described intervention resulted in improvement in mood and function in depressed patients with AMD and increased confidence in coping abilities among both depressed and nondepressed patients with AMD.

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