

## E.5 Non-pharmacological management

### E.5.1 Psychological therapies

RQ8: What is the effectiveness of psychological therapies for AMD?

<b>Bibliographic reference</b>	<b>Birk,T., Hickl,S., Wahl,H.W., Miller,D., Kammerer,A., Holz,F., Becker,S., Volcker,H.E., Development and pilot evaluation of a psychosocial intervention program for patients with age-related macular degeneration, Gerontologist, 44, 836-843, 2004</b>
Country/ies where the study was carried out	Germany
Study type	Non-randomised controlled trial
Aim of the study	To develop and evaluate a psychosocial intervention program for ARMD patients.
Study dates	Published 2004
Source of funding	Unclear
Sample size	22 participants Intervention group - 14 Comparison group - 8
Inclusion criteria	Bilateral age-related macular degeneration as documented by the assessment of the ophthalmologists involved in the study. Remaining visual acuity in the better eye had to be less than 20/70, Between 60 and 80 years of age Living in a private household.
Exclusion criteria	Severe terminal illnesses, Major hearing loss (not corrected or correctable by a hearing aid) Major cognitive impairment
Patient characteristics	Age Intervention group: 73.1 years Comparison group: 72.6 years  Gender (m)

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	<p>Intervention group: 5 Comparison group: 3</p> <p>The study did not report baseline characteristics for the following variables: Ethnic group Visual acuity Comorbidities affecting the eye (e.g. cataracts) Other co-morbidities (people with other sensory loss) Time since diagnosis of AMD Time since visual impairment due to AMD Disease stage</p>
Details	<p>Follow up was 7-9 weeks</p> <p>Positive and negative affect were assessed with the German version of the Positive and Negative Affect Schedule (PANAS; Watson, Clark, &amp; Tellegen, 1988). The PANAS positive and negative affect subscales consist of 10 adjectives connoting positive and negative emotions. Interviewers asked participants to indicate on a 5-point scale, ranging from 0 (not at all) to 4 (very often), how frequently they had experienced each emotion during the past week. We divided the total scores by the number of items.</p> <p>Depressive symptoms were assessed with the short version (15 items) of the Geriatric Depression Scale (GDS) suggested by Sheik and Yesavage (1986).</p> <p>ADL-IADL ability was assessed using a slightly modified version of a scale taken from the Multilevel Assessment Instrument (MAI; Lawton, Moss, Fulcomer, &amp; Kleban, 1982). The original scale was expanded to include four activities, which specifically addressed functional tasks that can be affected by vision loss (e.g., identifying coins and bills). The 18 items of this extended scale were assessed on a 4-point scale from 0 (performs task with no difficulty) to 3 (can perform task only with help) and summed them to create a total functional ability score (range 0–54). In addition, interviewers asked participants to rate their perceived autonomy on an 11-point Likert-type scale ranging from 0 (completely dependent) to 10 (completely independent).</p> <p>The Active Problem Orientation subscale from the Freiburger Fragebogen zur Krankheitsbewältigung, a standard German psycho-diagnostic instrument used to assess coping with illness (Muthny, 1989). This five-item measure addresses illness-</p>

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Interventions	<p>related behaviours such as seeking information on diseases and treatments or making plans to proactively cope with illnesses. Each item is rated on 5-point Likert-type format from 1 (not at all) to 5 (very strong).</p> <p>There were six major modules to the intervention programme:</p> <p>In the first module, group trainers taught progressive muscle relaxation skills to reduce anxiety stress symptoms frequently found in patients with age-related macular degeneration. This technique can be learned in two sessions and can also be practiced outside of group sessions and upon completion of the intervention program. Attendees also received an audiocassette for home training.</p> <p>In the second module, exchange of personal experiences in dealing with age-related macular degeneration was addressed in order to exploit the potential of the group setting where patients could learn from one another's coping efforts and advice. The goal of this module was to strengthen a group atmosphere founded on mutual understanding, role-taking behaviour, and the providing of help.</p> <p>The third module focused on the links between thought, affect, and behaviour in order to underscore the close interdependence of these systems. The task of the group leaders in this module was to stimulate the reflection and to keep the group and individual discussion in the "here and now."</p> <p>In the fourth module, the focus was on strategies toward making the most of available resources, improving the awareness of existing competencies, and developing sources of personal growth. For this purpose, the group leaders stimulated the attendees to actively imagine what kind of new plans of action would be possible for them and how they could enhance the probability of their own positive experiences.</p> <p>In the fifth module, systematic problem-solving strategies were taught in order to improve the general capacity of patients with age-related macular degeneration in the treatment group to deal with current and future problems in their personal lives. A major aspect of this classic cognitive-behaviour therapy was to circumscribe problems as clearly as possible and to concretely formulate new goals and respective problem-solving alternatives.</p> <p>In the sixth and final module, information on more practical issues in dealing with age-related macular such as learning more about available possibilities, home modification options, and the existence of self-help organizations was presented. Two group trainers with a strong background in clinical psychology ran the program.</p>
Results	<p>Mean differences and confidence intervals were calculated by the reviewer using the information provided within the study:</p> <p>Positive effect (mean change from T1-T2) Intervention group (n=14): -0.26</p>

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	<p>Comparison group (n=8): -0.14 Mean difference (95% CI): -0.12 (-0.58, 0.34)</p> <p>Negative effect (mean change from T1-T2) Intervention group (n=14): 0.1 Comparison group (n=8): -0.43 Mean difference (95% CI): 0.53 (0.13, 0.92)</p> <p>Depression (mean change from T1-T2) Intervention group (n=14): 1.4 Comparison group (n=8): -0.05 Mean difference (95% CI): 1.45 (0.01, 2.88)</p> <p>ADL-IADL (mean change from T1-T2) Intervention group (n=14): 1.3 Comparison group (n=8): -4.8 Mean difference (95% CI): 6.1 (1.31, 10.88)</p> <p>Perceived autonomy (mean change from T1-T2) Intervention group (n=14): -0.8 Comparison group (n=8): 1 Mean difference (95% CI): -1.8 (-3.56, -0.03)</p> <p>Active Problem Orientation Score (mean change from T1-T2) Intervention group (n=14): -1.4 Comparison group (n=8): 2.1 Mean difference (95% CI): -3.5 (-7.11, 0.11)</p>

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Overall Risk of Bias	<p>Risk of bias assessed using the Cochrane risk of bias tool</p> <p>Overall risk of bias: High risk (not randomised, not blinded, unclear if significant difference between comparison groups, Other information: none</p> <p>Was the allocation sequence adequately generated? No</p> <p>Was allocation adequately concealed? No</p> <p>Was knowledge of the allocated intervention adequately prevented during the study? No</p> <p>Were incomplete outcome data adequately addressed?- No</p> <p>Are reports of the study free of suggestion of selective outcome reporting? Yes</p> <p>Was the study apparently free of other problems that could put it at a high risk of bias? Selection bias: Unclear if statistical difference found between those who took part in the trial and those who did not. The study did not report on the important baseline characteristics of Ethnic group, Visual acuity, Comorbidities affecting the eye (e.g. cataracts), Other co-morbidities (people with other sensory loss), Time since diagnosis of AMD, Time since visual impairment due to AMD, and Disease stage. Attrition bias: Unclear if statistical difference found between those who dropped out and those who remained. Large proportional drop out (5 in intervention group, 3 in comparison group) Performance bias: unclear if comparison groups received the same care apart from intervention studied although study reports that the comparison group did not receive any other psychological or psychosocial therapy during the course of the study.</p>

<b>Bibliographic reference</b>	<b>Brody,B.L., Roch-Levecq,A.C., Gamst,A.C., Maclean,K., Kaplan,R.M., Brown,S.I., Self-management of age-related macular degeneration and quality of life: a randomized controlled trial, Archives of Ophthalmology, 120, 1477-1483, 2002</b>
Country/ies where the study was carried out	USA
Study type	Randomised controlled trial
Aim of the study	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.
Study dates	Published 2002

<b>Bibliographic reference</b>	<b>Brody,B.L., Roch-Levecq,A.C., Gamst,A.C., Maclean,K., Kaplan,R.M., Brown,S.I., Self-management of age-related macular degeneration and quality of life: a randomized controlled trial, Archives of Ophthalmology, 120, 1477-1483, 2002</b>
Source of funding	National Eye Institute
Sample size	Participants were randomised to the following: 12-hour self-management program (n = 86) Series of 12 hours of tape-recorded health lectures (n = 74) Waiting list (n = 72)
Inclusion criteria	Diagnosis of AMD by an ophthalmologist and confirmed by fundus photographs Visual acuity of 20/60 or worse in the better eye and 20/100 or worse in the other eye with habitual correction (i.e. current glasses) No other unstable eye disease or vision loss due to other eye disease Age 60 years or older Adequate hearing, with a hearing aid if necessary, to complete the interview and to respond in normal conversation Physical ability to come to an interview if wheelchair access transportation was provided No cognitive impairment as assessed by the Orientation-Memory Concentration Test No current alcohol abuse as assessed by the Short Michigan Alcoholism Screening Test
Exclusion criteria	None
Patient characteristics	Ethnic group - not reported  Age, mean $\pm$ SD Self-management group (n=86) - 80.73 $\pm$ 7.12 Tape recording group (n=74) - 81.21 $\pm$ 5.25 Wait list group (n=71) - 80.76 $\pm$ 5.75  Gender, M, % Self-management group (n=86) - 25 Tape recording group (n=74) - 25 Wait list group (n=71) - 28

<b>Bibliographic reference</b>	<b>Brody,B.L., Roch-Levecq,A.C., Gamst,A.C., Maclean,K., Kaplan,R.M., Brown,S.I., Self-management of age-related macular degeneration and quality of life: a randomized controlled trial, Archives of Ophthalmology, 120, 1477-1483, 2002</b>
	<p>Visual acuity (Snellen)  Self-management group (n=86) - 20/537  Tape recording group (n=74) - 20/599  Wait list group (n=71) - 20/485</p> <p>Comorbidities affecting the eye (e.g. cataracts) - not reported</p> <p>Other co-morbidities (people with other sensory loss) - not reported</p> <p>Time since diagnosis of AMD, months  Self-management group (n=86)- 96.84  Tape recording group (n=74)- 92.93  Wait list group (n=71)- 100.30</p> <p>Time since visual impairment due to AMD - not reported</p> <p>Disease stage - not reported</p>
<b>Details</b>	<p>Participants were randomly assigned to 1 of 3 groups: self-management, tape-recorded health education program, or to a waiting list (control group).</p> <p><b>Primary Outcome Measure</b>  The Profile of Mood States (POMS) was used to measure mood. This is a 65-item self-report inventory designed to assess emotional distress during the previous week. 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.</p> <p><b>Secondary Outcome Measures</b></p>

<b>Bibliographic reference</b>	<b>Brody,B.L., Roch-Levecq,A.C., Gamst,A.C., Maclean,K., Kaplan,R.M., Brown,S.I., Self-management of age-related macular degeneration and quality of life: a randomized controlled trial, Archives of Ophthalmology, 120, 1477-1483, 2002</b>
	<p>The National Eye Institute Visual Function Questionnaire (NEI-VFQ) was used to measure effects on everyday functioning. This is a multifaceted functional measure of health-related quality of life in relation to vision. The total score can range from 0 to 100, where 0 represents the worst possible functioning and 100 the best.</p> <p>Mediator Variables</p> <p>The following were studied as mediators of the effects of the self-management program on mood and function:</p> <p>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.</p> <p>Life Orientation Test–Revised (LOT-R). The LOT-R is a 10-item measure that assesses optimistic vs pessimistic life outlook. Scores range from 0 to 24. Higher scores indicate a more optimistic approach to life.</p> <p>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).</p>
<b>Interventions</b>	<p>Participants were randomly assigned to 1 of 3 groups: self-management, tape-recorded health education program, or to a waiting list (control group).</p> <p>The 6-week self-management program:</p> <p>8 to 10 participants met weekly for 2-hour sessions led by an experienced professional in public health and behavioural medicine. 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, e.g., ophthalmology, rehabilitation, nutrition, exercise physiology, and low vision optometry. In the group problem-solving component, participants were guided through a hierarchy of behavioural challenges to improve problem-solving skills with the support and experience of peers and professionals. The intervention was composed of both cognitive and behavioural components.</p> <p>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. Re-evaluation of perceived barriers to independence was encouraged, and positive challenges were provided from peers and group leaders.</p>



<b>Bibliographic reference</b>	<b>Brody,B.L., Roch-Levecq,A.C., Gamst,A.C., Maclean,K., Kaplan,R.M., Brown,S.I., Self-management of age-related macular degeneration and quality of life: a randomized controlled trial, Archives of Ophthalmology, 120, 1477-1483, 2002</b>			
	<p>Behavioural components included behavioural skills training in communicating with others about visual disability, handling a variety of challenges associated with AMD, and requesting assistance when needed. Modelled after successful psychosocial interventions with chronic disease, vignettes were presented to the group, covering various problems encountered by people with AMD. In addition, participants presented situations they had faced. Adaptive behaviours were modelled for the participants. A simple exercise program designed for this population was also incorporated into the program.</p> <p>Tape recorded health-education</p> <p>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.</p> <p>Waiting list</p> <p>One further control group remained on a waiting list.</p>			
Results		Baseline, mean (SD)	6-weeks, mean (SD)	Mean Difference
	Profile of Mood States (POMS), total score			
	Self-management (n=86)	60.84 ± 29.69	53.75 ± 24.51	-7.09 ± 21.83 (95% CI, -15.39 to -1.21)
	Control group (n=144)	54.86 ± 30.97	58.27 ± 34.17	3.41 ± 21.54 (95% CI, -2.39 to 9.21)
	25-Item National Eye Institute- visual functioning (NEI-VFQ), total			
	Self-management (n=86)	59.72 ± 13.18	60.76 ± 12.69	1.02 ± 6.80 (95% CI -0.44 to 2.48)

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Control group (n=145)	58.80 ± 13.30	58.87 ± 13.23	0.07 ± 7.5 (95% CI -1.16 to 1.31)
Age-related Macular Degeneration Self-Efficacy Scale, total score			
Self-management (n=86)	70.89 ± 16.01	76.23 ± 13.56	5.34 ± 12.17 (95% CI 2.73 to 7.95)
Control group (n=145)	71.60 ± 15.36	72.72 ± 15.77	1.12 ± 11.85 (95% CI, -0.82 to 3.07)
Depressed Participants at Baseline (as defined by SCID)			
	Baseline, mean (SD)	6-weeks, mean (SD)	Mean Difference
Profile of Mood States (POMS), total score			
Self-management (n=20)	80.24 ± 25.34	65.10± 19.25	-15.41 ± 28.91 (-2867 to -1.61)
Control group (n=34)	65.77 ± 33.89	73.12 ± 40.51	7.35 ± 21.94 (-31 to 15.00)
25-Item National Eye Institute- visual functioning			
Self-management (n=20)	49.97+ 11.32	53.51 ± 11.60	3.58 ± 8.17 (-30 to 735)

Bibliographic reference	Brody,B.L., Roch-Levecq,A.C., Gamst,A.C., Maclean,K., Kaplan,R.M., Brown,S.I., Self-management of age-related macular degeneration and quality of life: a randomized controlled trial, Archives of Ophthalmology, 120, 1477-1483, 2002			
	Control group (n=34)	49.59 ± 13.61	47.94 ± 11.61	1.65 ± 8.53 (-4.62 to 1.33)
	Non-depressed Participants at Baseline (as defined by SCID)			
		Baseline, mean (SD)	6-weeks, mean (SD)	Mean Difference
	Profile of Mood States (POMS), total score			
	Self-management (n=66)	41.45±24.70	42.40 ± 23.57	0.94 ± 17.86 (-3.44 to 5.33)
	Control group (n=110)	43.97 ± 28.32	43.42 ± 28.71	-0.55 ± 21.23 (-4.56 to 3.46)
	25-Item National Eye Institute- visual functioning			
	Self-management (n=66)	62.67 ± 12.32	62.94 ± 12.25	0.261±6.21 (-126 to 1.79)
	Control group (n=110)	61.53 ± 12.00	62.17 ± 1.1.89	0.63±7.14 (-71 to 1.98)
Overall Risk of Bias	<p>Risk of bias assessed using the Cochrane risk of bias tool</p> <p>Overall risk of bias: Initial randomisation was not stratified for presence of depression at initial outset (randomisation still intact however less powerful). Single masked study, however investigators were kept masked to the study allocation. The study reports "there were no differences in demographic or clinical characteristics in the potential participants who enrolled in the study and those who declined. The subjects who completed the study did not differ in demographic or clinical characteristics from those who dropped out." The study did not provide outcomes for two of its planned measures (the DSSI</p>			

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	<p>and LOT-R), only total scores were reported. In a post hoc decision, the study merged the two control groups. One which was given tape recording information and one which was put on a waiting list. This was because there was found to be no difference between the groups on either baseline or in the resulting change scores.</p> <p>Was the allocation sequence adequately generated? Yes</p> <p>Was allocation adequately concealed? Yes</p> <p>Was knowledge of the allocated intervention adequately prevented during the study? No</p> <p>Were incomplete outcome data adequately addressed?- Yes</p> <p>Are reports of the study free of suggestion of selective outcome reporting? No (but only with regard to the "mediator measures", as opposed to the primary outcome measures).</p> <p>Was the study apparently free of other problems that could put it at a high risk of bias? Unclear</p> <p>Other information- none</p>

<b>Bibliographic reference</b>	<b>Brody,B.L., Roch-Levecq,A.C., Kaplan,R.M., Moutier,C.Y., Brown,S.I., Age-related macular degeneration: self-management and reduction of depressive symptoms in a randomized, controlled study, Journal of the American Geriatrics Society, 54, 1557-1562, 2006</b>
Country/ies where the study was carried out	USA
Study type	Randomised controlled trial
Aim of the study	To assess the effectiveness of a self-management program for age-related macular degeneration (AMD) in reducing depressive symptoms.
Study dates	Published 2006
Source of funding	Financed in part by grants from the National Eye Institute.
Sample size	Participants taken from the trial described in: Brody et al Self-management of age-related macular degeneration and quality of life: a randomized controlled trial (2002). A trial of 231 participants in the AMD self-management study. The present investigation focused on a subset of 32 depressed subjects who had been randomised to: An AMD self-management programme (n=12)

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	One of two control groups (n=20)
Inclusion criteria	Subjects were included if at baseline they had met criteria from the Structured Clinical Interview for the Diagnostic and Statistical Manual of Mental Disorders (SCID) for major or minor depressive disorder and had a score indicating significant depressive symptoms. Other inclusion criteria: Diagnosis of AMD by an ophthalmologist, confirmed using fundus photographs Visual acuity of 20/60 or worse in the better eye Visual acuity of 20/100 or worse in the worse eye With habitual correction (i.e. current glasses)
Exclusion criteria	Other unstable eye disease Vision loss due to other eye disease Aged 60 or older Cognitive impairment as assessed using the orientation-memory concentration test
Patient characteristics	Ethnic group: Not reported  Age, y, mean $\pm$ SD Self-management group (n=12) - 81.2 $\pm$ 9.56 Tape recording group (n=8) - 81.9 $\pm$ 5.36 Wait list group (n=12) - 81.6 $\pm$ 7.10  Gender, M, % Self-management group (n=12) - 41.7% Tape recording group (n=8) - 25.0% Wait list group (n=12) - 33.3%  Visual acuity, Snellen rating

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	<p>Self-management group (n=12) - 430  Tape recording group (n=8) - 350  Wait list group (n=12) - 335</p> <p>Comorbidities affecting the eye - no detail given on type of co-morbidities</p> <p>Other co-morbidities (people with other sensory loss) - no further detail given on other co-morbidities  Self-management group (n=12) - 91.7%  Tape recording group (n=8) - 100%  Wait list group (n=12) - 83.3%</p> <p>Time since diagnosis of AMD - not reported</p> <p>Time since visual impairment due to AMD (months)  Self-management group (n=12) - 47.3  Tape recording group (n=8) - 41.0  Wait list group (n=12) - 64.0</p> <p>Disease stage - not reported</p>
Details	<p>Participants were randomly assigned to 1 of 3 groups: self-management, tape-recorded health education program, or to a waiting list (control group).</p> <p>Primary Outcome Measure  The Profile of Mood States (POMS) was used to measure mood. This is a 65-item self-report inventory designed to assess emotional distress during the previous week. 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.</p> <p>Secondary Outcome Measures</p>

<b>Bibliographic reference</b>	<p><b>Brody,B.L., Roch-Levecq,A.C., Kaplan,R.M., Moutier,C.Y., Brown,S.I., Age-related macular degeneration: self-management and reduction of depressive symptoms in a randomized, controlled study, Journal of the American Geriatrics Society, 54, 1557-1562, 2006</b></p>
	<p>The National Eye Institute Visual Function Questionnaire (NEI-VFQ) was used to measure effects on everyday functioning. This is a multifaceted functional measure of health-related quality of life in relation to vision. The total score can range from 0 to 100, where 0 represents the worst possible functioning and 100 the best.</p> <p>Mediator Variables</p> <p>The following were studied as mediators of the effects of the self-management program on mood and function:</p> <p>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.</p> <p>Life Orientation Test–Revised (LOT-R). The LOT-R is a 10-item measure that assesses optimistic vs pessimistic life outlook. Scores range from 0 to 24. Higher scores indicate a more optimistic approach to life.</p> <p>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).</p>
<b>Interventions</b>	<p>Participants were randomly assigned to 1 of 3 groups: self-management, tape-recorded health education program, or to a waiting list (control group).</p> <p>The 6-week self-management program:</p> <p>8 to 10 participants met weekly for 2-hour sessions led by an experienced professional in public health and behavioural medicine. 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, e.g. ophthalmology, rehabilitation, nutrition, exercise physiology, and low vision optometry. In the group problem-solving component, participants were guided through a hierarchy of behavioural challenges to improve problem-solving skills with the support and experience of peers and professionals. The intervention was composed of both cognitive and behavioural components.</p> <p>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. Re-evaluation of perceived barriers to independence was encouraged, and positive challenges were provided from peers and group leaders.</p>

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	<p>Behavioural components included behavioural skills training in communicating with others about visual disability, handling a variety of challenges associated with AMD, and requesting assistance when needed. Modelled after successful psychosocial interventions with chronic disease, vignettes were presented to the group, covering various problems encountered by people with AMD. In addition, participants presented situations they had faced. Adaptive behaviours were modelled for the participants. A simple exercise program designed for this population was also incorporated into the program.</p> <p>Tape recorded health-education</p> <p>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.</p> <p>Waiting list</p> <p>One further control group remained on a waiting list.</p> <p>Because at baseline, the randomisation resulted in no statistically significant differences between three groups on demographic and clinical characteristics, the two control groups were collapsed to become one (n=20).</p>			
<b>Results</b>		Baseline, mean (SD)	6-months, mean (SD)	Mean Difference
	Geriatric Depression Scale, total score			
	Self-management (n=12)	7.50 ± 2.19	4.58 ± 2.42	-2.92 ± 3.26
	Control group (n=20)	7.80 ± 2.35	6.80 ± 2.96	-1.00 ± 3.78
	25-Item National Eye Institute- visual functioning			
	Self-management (n=12)	44.82 ± 8.39	50.52 ± 10.04	5.70 ± 13.08
	Control group (n=20)	44.64 ± 14.56	47.98 ± 11.66	3.34 ± 18.65
	Age-related Macular Degeneration Self-Efficacy Scale, total score			



Bibliographic reference	Brody,B.L., Roch-Levecq,A.C., Kaplan,R.M., Moutier,C.Y., Brown,S.I., Age-related macular degeneration: self-management and reduction of depressive symptoms in a randomized, controlled study, Journal of the American Geriatrics Society, 54, 1557-1562, 2006			
	Self-management (n=12)	55.76 ± 18.81	73.07 ± 13.75	17.31 ± 23.30
	Control group (n=20)	61.67 ± 14.84	65.62 ± 18.15	3.95 ± 23.44
	11-item Duke Social Support Index (social support), total score			
	Self-management (n=12)	29.16 ± 6.61	34.63 ± 9.29	5.47 ± 11.40
	Control group (n=20)	27.60 ± 8.76	27.35 ± 11.69	-0.25 ± 14.61
	Life Orientation Test- Revised (optimism), total score			
	Self-management (n=12)	10.25 ± 3.30	9.63 ± 2.54	-0.62 ± 4.16
	Control group (n=20)	9.40 ± 2.47	9.65 ± 2.73	0.25 ± 3.68
Overall Risk of Bias	<p>Risk of bias assessed using the Cochrane risk of bias tool</p> <p>Overall risk of bias: Randomisation process was mostly described in another study. Initial randomisation was not stratified for presence of depression at initial outset (randomisation still intact however less powerful). Single masked study, however investigators were kept masked to the study allocation. The study reports "there were no differences in demographic or clinical characteristics in the potential participants who enrolled in the study and those who declined. The subjects who completed the study did not differ in demographic or clinical characteristics from those who dropped out." No apparent selective reporting of outcomes. In a post hoc decision, the study merged the two control groups. One which was given tape recording information and one which was put on a waiting list. This was because there was found to be no difference between the groups on either baseline or in the resulting change scores.</p> <p>Other information: This study reports a subset from a previously performed randomised controlled trial, but comparing the two studies it appears to have only included a proportion of the depressed population identified in the prior study. Unclear if the differences were systematic. If not randomisation may have been broken.</p> <p>Was the allocation sequence adequately generated? Yes</p> <p>Was allocation adequately concealed? Yes</p> <p>Was knowledge of the allocated intervention adequately prevented during the study? No</p> <p>Were incomplete outcome data adequately addressed? Yes</p>			

<b>Bibliographic reference</b>	<b>Brody,B.L., Roch-Levecq,A.C., Kaplan,R.M., Moutier,C.Y., Brown,S.I., Age-related macular degeneration: self-management and reduction of depressive symptoms in a randomized, controlled study, Journal of the American Geriatrics Society, 54, 1557-1562, 2006</b>
	Are reports of the study free of suggestion of selective outcome reporting? Yes Was the study apparently free of other problems that could put it at a high risk of bias? Unclear

<b>Bibliographic reference</b>	<b>Rovner,B.W., Casten,R.J., Hegel,M.T., Leiby,B.E., Tasman,W.S., Preventing depression in age-related macular degeneration, Archives of General Psychiatry, 64, 886-892, 2007</b>
Country/ies where the study was carried out	USA
Study type	Randomised controlled trial
Aim of the study	To determine whether problem solving treatment can prevent depressive disorders in patients with recent vision loss.
Study dates	Published 2007
Source of funding	National Institute of Mental Health; National Eye Institute; Farber Institute for Neurosciences.
Sample size	206 participants: Problem-solving treatment group (n=105) Usual care (n=101)
Inclusion criteria	Older than 64 years Neovascular AMD in one eye diagnosed within the preceding 6 months, by FA Pre-existing AMD in the fellow eye
Exclusion criteria	DSM-IV–defined diagnoses of depressive disorders or current treatment for depression Cognitive impairment Confounding eye conditions
Patient characteristics	Ethnic group, white, % Problem solving treatment (n=105): 98.1 Usual care (n=101): 99.0

Bibliographic reference	Rovner,B.W., Casten,R.J., Hegel,M.T., Leiby,B.E., Tasman,W.S., Preventing depression in age-related macular degeneration, Archives of General Psychiatry, 64, 886-892, 2007
	<p>Age, mean (SD), y            Problem solving treatment (n=105) - 81.3 (5.4)            Usual care (n=101) - 81.0</p> <p>Gender, female, %            Problem solving treatment (n=105): 65.7            Usual care (n=101): 74.3</p> <p>Visual acuity, mean (SD), best distance acuity, logMAR            Problem solving treatment (n=105): 0.56 (0.33)            Usual care (n=101): 0.64 (0.44)</p> <p>Comorbidities affecting the eye (e.g. cataracts) - not reported</p> <p>Hamilton Depression Rating Scale score            Problem solving treatment (n=105): 2.10 (2.07)            Usual care (n=101): 2.25 (2.36)</p> <p>Underwent previous depression treatment, %            Problem solving treatment (n=105): 3.4            Usual care (n=101): 1.5</p> <p>Time since diagnosis of AMD - not reported</p> <p>Time since visual impairment due to AMD - not reported</p> <p>Disease stage - all neovascular</p>

<b>Bibliographic reference</b>	<b>Rovner,B.W., Casten,R.J., Hegel,M.T., Leiby,B.E., Tasman,W.S., Preventing depression in age-related macular degeneration, Archives of General Psychiatry, 64, 886-892, 2007</b>
Details	<p>Follow up Follow up was 6-months</p> <p>Assessments Research nurses with extensive training in psychiatry and ophthalmology obtained informed consent and completed all assessments in subjects' homes.</p> <p>The primary outcome was a DSM-IV–defined diagnosis of major or minor depression. The research nurses administered the modified Schedule for Affective Disorders and Schizophrenia and the Structured Interview Guide for the Hamilton Depression Rating Scale (HDRS) to rule out depression at baseline, to obtain history of depression treatment, and to diagnose a depressive disorder at 2 and 6 months. Interrater reliability for nurse ratings was established (<math>\kappa = 0.96</math>). The 24-item HDRS was also used to quantify depressive symptoms. Possible scores ranged from 0 to 75, with higher scores indicating more severe depression. Scores less than 7 are considered normal.</p>
Interventions	<p>Problem-solving treatment A manual-driven psychological treatment that teaches problem-solving skills. It addresses negative perceptions that may interfere with finding practical solutions to problems and teaches the following problem-solving skills:</p> <ol style="list-style-type: none"> <li>(1) Defining problems</li> <li>(2) Establishing realistic goals</li> <li>(3) Generating, choosing, and implementing solutions</li> <li>(4) Evaluating outcomes</li> </ol> <p>Subjects are encouraged to use these skills routinely to develop practical compensatory strategies to achieve valued functional goals and thereby prevent depression. Problem-solving treatment–trained therapists (2 nurses and 1 master’s-level counsellor) delivered 6 in-home PST sessions (45-60 minutes long) during 8 weeks to subjects randomized to PST. All therapists received extensive training, which included reviewing the PST treatment manual, watching training videotapes, and treating 5 practice patients.</p> <p>Usual care Subjects randomized to both PST and usual care continued to receive treatment as usual from their ophthalmologists or other health care providers. Usual care subjects were offered PST once the clinical trial was completed.</p> <p>During the trial, no subjects in either treatment group received outside specialty mental health treatment. There were no statistically significant differences in the proportions of subjects (PST vs usual care) who received low-vision rehabilitation, used optical devices, or were treated with antidepressant medications.</p>

Bibliographic reference	Rovner,B.W., Casten,R.J., Hegel,M.T., Leiby,B.E., Tasman,W.S., Preventing depression in age-related macular degeneration, Archives of General Psychiatry, 64, 886-892, 2007						
Results		2 MONTH FU			6-MONTH FU		
	Measure	Problem solving (n=105)	Usual care (n=101)	Odds ratio (95% CI)	Problem solving	Usual care	Odds ratio (95% CI)
	Depression, No (%)	11 (11.5)	23 (23.2)	0.39 (0.17-0.92)	20 (21.1)	26 (27.4)	0.65 (0.33-1.39)
	No. of lost activities (%)	22 (23.2)	37 (37.4)	0.48 (0.25- 0.96)	29 (30.5)	42 (44.2)	0.53 (0.28-1.01)
			2 MONTH FU		6-MONTH FU		
	Measure		Problem solving	Usual care	Problem solving	Usual care	
	Mean (SE) change in NEI VFQ-17 score		0.96 (7.97)	-1.35 (7.80)	-0.97 (8.88)	-2.45 (9.64)	
	Mean (SD) change in HDRS score		-0.35 (2.88)	-0.58 (2.96)	-1.03 (4.12)	-1.04 (4.32)	
	Overall Risk of Bias	<p>Risk of bias assessed using the Cochrane risk of bias tool</p> <p>Overall risk of bias: Moderate (single-blind and study did not report baseline characteristics of time since diagnosis of AMD and time since visual impairment due to AMD)</p> <p>Was the allocation sequence adequately generated? Yes</p> <p>Was allocation adequately concealed? Yes</p> <p>Was knowledge of the allocated intervention adequately prevented during the study? No - single blind</p> <p>Were incomplete outcome data adequately addressed? Yes</p> <p>Are reports of the study free of suggestion of selective outcome reporting? Yes</p>					

<b>Bibliographic reference</b>	<b>Rovner,B.W., Casten,R.J., Hegel,M.T., Leiby,B.E., Tasman,W.S., Preventing depression in age-related macular degeneration, Archives of General Psychiatry, 64, 886-892, 2007</b>
	Was the study apparently free of other problems that could put it at a high risk of bias? Selection bias: No statistical difference found between those who took part in the trial and those who did not. The study did not report on the important baseline characteristics of time since diagnosis and time since visual impairment. Attrition bias: no statistical difference found between those who dropped out and those who remained. Performance bias: unclear if comparison groups received the same care apart from intervention studied although there was no statistical difference for the number who received low-vision rehabilitation, used optical devices, or were treated with antidepressant medications between comparison groups. Other information - none

<b>Bibliographic reference</b>	<b>Rovner,B.W., Casten,R.J., Hegel,M.T., Massof,R.W., Leiby,B.E., Ho,A.C., Tasman,W.S., Improving function in age-related macular degeneration: a randomized clinical trial, Ophthalmology, 120, 1649-1655, 2013</b>
Country/ies where the study was carried out	USA
Study type	Randomised controlled trial
Aim of the study	To compare the efficacy of problem-solving therapy (PST) with supportive therapy (ST) to improve targeted vision function in age-related macular degeneration (AMD).
Study dates	Published 2013
Source of funding	Supported by NEI grant
Sample size	241 participants: Problem solving treatment group: 121 Supportive therapy group: 120
Inclusion criteria	Age 65 years or older Bilateral AMD (neovascular and/or geographic atrophy) Visual acuity between 20/70 and 20/400 [inclusive; (best corrected)] in the better-seeing eye, and no lower acuity limit in the fellow eye Moderate difficulty in at least one valued vision-function goal (e.g., reading mail, attending social activities)
Exclusion criteria	Presence of uncontrolled glaucoma, diabetic retinopathy, or planned cataract surgery within 6 months

<b>Bibliographic reference</b>	<b>Rovner,B.W., Casten,R.J., Hegel,M.T., Massof,R.W., Leiby,B.E., Ho,A.C., Tasman,W.S., Improving function in age-related macular degeneration: a randomized clinical trial, Ophthalmology, 120, 1649-1655, 2013</b>
	<p>Cognitive impairment on an abbreviated version of the Mini-Mental Status Examination (MM blind) that omits vision-dependent items</p> <p>Presence of a medical condition that would preclude participation</p> <p>Residence in a skilled nursing facility</p>
Patient characteristics	<p>Age (mean years, standard deviation)</p> <p>Problem solving treatment group (n=121): 82.7 (6.6)</p> <p>Supportive therapy group (n=120): 82.8 (7.3)</p> <p>Female (n, %)</p> <p>Problem solving treatment group (n=121): 82 (67.8)</p> <p>Supportive therapy group (n=120): 71 (59.2)</p> <p>Ethnicity, White (n, %)</p> <p>Problem solving treatment group (n=121): 120 (99.2)</p> <p>Supportive therapy group (n=120): 119 (99.2)</p> <p>Patient Health Questionnaire-9 (depression)</p> <p>Problem solving treatment group (n=121): 1.4 (2.7)</p> <p>Supportive therapy group (n=120): 1.2 (2.3)</p> <p>Number of resources/rehabilitative devices used</p> <p>Problem solving treatment group (n=121): 5.1 (3.3)</p> <p>Supportive therapy group (n=120): 4.7 (3.0)</p> <p>Chronic Disease Score (medical comorbidity)</p> <p>Problem solving treatment group (n=121): 5.5 (2.8)</p> <p>Supportive therapy group (n=120): 5.7 (3.1)</p>

<b>Bibliographic reference</b>	<b>Rovner,B.W., Casten,R.J., Hegel,M.T., Massof,R.W., Leiby,B.E., Ho,A.C., Tasman,W.S., Improving function in age-related macular degeneration: a randomized clinical trial, Ophthalmology, 120, 1649-1655, 2013</b>
	<p>Best eye, distance (logMAR)  Problem solving treatment group (n=121): 0.58 (0.29)  Supportive therapy group (n=120): 0.57 (0.28)</p> <p>Best eye, near (logMAR)  Problem solving treatment group (n=121): 0.62 (0.25)  Supportive therapy group (n=120): 0.62 (0.25)</p> <p>The study did not report baseline characteristics for:  Time since diagnosis of AMD  Time since visual impairment due to AMD  Disease stage</p>
Details	<p>Follow up was 3 months and 6 months  Primary outcome  Vision function goals  The Targeted Vision Function (TVF) goals that subjects valued but found difficult to achieve. To derive the TVF measure, at baseline subjects completed the Activities Inventory, which is a structured vision function questionnaire that asks patients to rate the value and difficulty of 48 vision function goals (e.g., daily meal preparation) and the tasks (e.g., seeing stove settings) that are required to achieve them. Higher average scores indicate greater disability. At each outcome assessment subjects again rated the difficulty of the same targeted goals and the average TVF score was calculated. In this way, TVF was targeted and tailored, measured in a standardized way, and allowed subjects to vary in the number of TVF goals they select at baseline.</p> <p>Secondary Outcomes  The National Eye Institute Vision Function Questionnaire-25 plus Supplement (NEI VFQ).  This version of the NEI VFQ consists of 39 items that assess self-reported vision function and vision-related quality of life (QoL). The latter yields a multidimensional index of vision-related health comprised of social functioning (i.e., social interactions), mental health (i.e., worry, frustration), role difficulties (i.e., accomplishing less), and dependency (i.e., relying more on others) due to vision loss. Scores range from 0 to 100, with higher scores indicating better function.</p>



<b>Bibliographic reference</b>	<b>Rovner,B.W., Casten,R.J., Hegel,M.T., Massof,R.W., Leiby,B.E., Ho,A.C., Tasman,W.S., Improving function in age-related macular degeneration: a randomized clinical trial, Ophthalmology, 120, 1649-1655, 2013</b>
	<p>Vision Status  Vision was assessed using a standardized battery of vision tests and standardized lighting to assess distance and near visual acuity, contrast sensitivity, and the size and location of central scotomas. Visual acuity was measured using the Lighthouse Ferris-Bailey Early Treatment Diabetes Retinopathy Study (ETDRS) chart at a distance of 10 feet. For near acuity the ETDRS chart calibrated for 40 cm was used.</p> <p>Physical Health Status  The Chronic Disease Score, which provides an objective measure of medical comorbidity based on a weighted sum of medications taken for chronic illness was calculated. Higher scores indicate worse medical morbidity.</p> <p>Psychosocial Status  To assess depression the Patient Health Questionnaire-9 was used, which yields a continuous measure of depression severity. Scores range from 0 to 27, with higher scores indicating worse depression.</p> <p>Control  The Optimization in Primary and Secondary Control Scale (OPS) to assess subjects' control (i.e., coping) strategies. The OPS is divided into 4 control strategies, each comprised of 8 items rated from 0 ("never true") to 4 ("almost always true"), yielding a range of 0 to 32; higher scores indicate greater use of the particular strategy. Selective primary control refers to the investment of behavioural resources (i.e., time, effort, skills) to pursue a goal (e.g., "I do whatever I can to continue my everyday activities despite my vision problem."). Selective secondary control serves to maintain commitment to a goal in the face of obstacles (e.g., "I think how important it is to me to keep up my daily activities in spite of my vision problem."). Compensatory primary control refers to asking for help from others or using assistive devices (e.g., "If I'm having trouble doing something because of my vision problem, I look for a device or aid that will help get it done."). Compensatory secondary control refers to goal disengagement when goals become unattainable (e.g., "I can accept that there are things I can no longer do since I started having problems with my vision.").</p>
<b>Interventions</b>	<p>Problem-Solving Therapy (PST)  PST teaches problem-solving skills in a structured way to enable a patient to systematically identify his or her problems, generate alternative solutions for each problem, select the best solution, develop and conduct a plan, and evaluate whether the problem is solved. In this study, the PST therapist and subject discussed the functional problems caused by vision loss and used the following problem-solving steps to reduce the difficulty of vision-dependent tasks:</p> <ol style="list-style-type: none"> <li>1) clarifying the problems associated with the task</li> <li>2) establishing a realistic goal toward improvement of task performance</li> <li>3) generating multiple solution alternatives</li> </ol>

<b>Bibliographic reference</b>	<b>Rovner,B.W., Casten,R.J., Hegel,M.T., Massof,R.W., Leiby,B.E., Ho,A.C., Tasman,W.S., Improving function in age-related macular degeneration: a randomized clinical trial, Ophthalmology, 120, 1649-1655, 2013</b>			
	<p>4) implementing decision-making guidelines  5) choosing the preferred solution(s)  6) implementing the preferred solutions(s)  7) evaluating the outcome</p> <p>The PST therapist helped subjects to develop feasible solutions and reviewed available rehabilitative services and devices to inform the process of generating solutions. The aim was to have subjects incorporate the problem-solving method of reasoning as a routine, often-recruited approach to solving future as well as current function-related problems.</p> <p>Control strategies</p> <p>ST is a structured, standardized, psychological treatment that controls for nonspecific treatment effects. ST resembles PST in all ways but for PST's problem-solving skills training. Both interventions are based on written treatment manuals and similar in dose and intensity of attention (i.e. number and duration of sessions). ST is nondirective, supportive, and facilitates personal expression and conveys empathy, respect, and optimism (i.e. a general sense that things can get better). The ST therapist informs subjects that ST's purpose is to explore the impact of vision loss on their lives. The goals were to facilitate and deepen knowledge of subjects' life situations and their relationship to illness, disability, retirement, social isolation and vision loss. The ST therapists created an accepting, non-judgmental, empathic environment by using supportive statements, reflective listening, and empathic communications. In contrast to PST, there was no discussion of vision function goals, problem solving, or low vision rehabilitative strategies.</p>			
Results	Primary and Secondary Outcomes at Month 3 and Month 6			
	Treatment Group	Baseline (SD)	Month 3 (SD)	Month 6 (SD)
	TVF			
	PST (n=121)	2.71 (0.52)	2.18 (0.88)	2.18 (0.95)
	ST (n=120)	2.73 (0.52)	2.14 (0.96)	2.15 (0.96)
	25.3			
	PST	0.69 (0.94)	0.99 (1.2)	0.93 (1.2)
	ST	0.70 (0.93)	1.02 (1.2)	0.92 (1.2)

Bibliographic reference	Rovner,B.W., Casten,R.J., Hegel,M.T., Massof,R.W., Leiby,B.E., Ho,A.C., Tasman,W.S., Improving function in age-related macular degeneration: a randomized clinical trial, Ophthalmology, 120, 1649-1655, 2013			
NEI-VFQ Total Score				
PST	66.2 (14.3)	66.6 (14.9)	66.4 (16.7)	
ST	65.8 (14.2)	65.2 (16.2)	64.8 (17.4)	
NEI-VFQ QoL Social Functioning				
PST	80.9 (22.3)	78.1 (22.8)	76.17 (25.1)	
ST	80.9 (23.9)	74.1 (25.6)	73.64 (28.0)	
NEI-VFQ QoL Mental Health				
PST	60.3 (27.4)	66.9 (26.7)	68.0 (25.1)	
ST	56.8 (27.3)	60.9 (28.0)	62.5 (27.4)	
NEI-VFQ QoL Role Functioning				
PST	57.8 (20.0)	57.1 (20.2)	56.9 (20.6)	
ST	55.7 (20.1)	58.3 (21.0)	57.6 (22.7)	
NEI-VFQ QoL Dependency				
PST	70.0 (29.3)	73.0 (28.8)	72.6 (30.1)	
ST	66.6 (31.9)	65.6 (30.6)	66.5 (30.5)	
Control Strategies: Selective Primary Control				
PST	22.4 (2.2)	21.5 (3.2)	21.1 (3.5)	
ST	22.2 (2.6)	21.5 (3.3)	22.1 (2.7)	
Control Strategies: Compensatory Primary Control				

Bibliographic reference	Rovner,B.W., Casten,R.J., Hegel,M.T., Massof,R.W., Leiby,B.E., Ho,A.C., Tasman,W.S., Improving function in age-related macular degeneration: a randomized clinical trial, <i>Ophthalmology</i> , 120, 1649-1655, 2013			
	PST	26.7 (6.1)	25.5 (6.6)	25.3 (6.4)
	ST	26.8 (6.0)	24.1 (6.7)	25.1 (6.3)
	Control strategies: Compensatory Secondary Control			
	PST	21.6 (4.1)	21.6 (4.0)	21.9 (4.8)
	ST	22.1 (3.8)	20.2 (4.6)	20.7 (4.9)
	Control Strategies: Selective Secondary Control			
	PST	30.0 (5.0)	29.0 (5.3)	28.6 (5.7)
	ST	30.1 (4.8)	28.3 (5.6)	28.5 (5.4)
Overall Risk of Bias	<p>Risk of bias assessed using the Cochrane risk of bias tool</p> <p>Overall risk of bias: Moderate</p> <p>Other information: None</p> <p>Was the allocation sequence adequately generated? Yes</p> <p>Was allocation adequately concealed? Yes</p> <p>Was knowledge of the allocated intervention adequately prevented during the study? No (investigator "single" blind, the project director, statistician, and therapists were aware of treatment assignment)</p> <p>Were incomplete outcome data adequately addressed? Yes</p> <p>Are reports of the study free of suggestion of selective outcome reporting? Yes</p> <p>Was the study apparently free of other problems that could put it at a high risk of bias? Single masked study. Attrition: Unclear if differences in demographic or clinical characteristics in the potential participants who enrolled in the study and those who were lost to follow up, loss to follow up was relatively low. Groups did not appear to have received different treatment other than the intervention of interest. The study did not report baseline characteristics for: time since diagnosis of AMD, time since visual impairment due to AMD, disease stage.</p>			

<b>Bibliographic reference</b>	<b>Rovner,B.W., Casten,R.J., Hegel,M.T., Massof,R.W., Leiby,B.E., Ho,A.C., Tasman,W.S., 20150326, Low vision depression prevention trial in age-related macular degeneration: a randomized clinical trial, Ophthalmology, 121, 2204-2211, 2014</b>
Country/ies where the study was carried out	USA
Study type	Randomised controlled trial
Aim of the study	To compare the efficacy of behaviour activation (BA) + low vision rehabilitation (LVR) with supportive therapy (ST) + LVR to prevent depressive disorders in patients with age-related macular degeneration (AMD).
Study dates	Published 2014
Source of funding	NEI grant
Sample size	188 participants were included: Behavioural activation plus low vision rehabilitation (n = 96) Supportive therapy plus low vision rehabilitation (n = 92)
Inclusion criteria	Age >65 years Bilateral AMD (either neovascular disease or geographic atrophy) Best-corrected visual acuity <20/70 in the better seeing eye >5 antiangiogenic injections if the better eye had neovascular disease, or no injections in the previous 3 months Moderate difficulty performing a valued vision-dependent activity Sub-threshold depressive symptoms, defined as a Patient Health Questionnaire-9 score of >5, or depressed mood or anhedonia several days per week.
Exclusion criteria	Ongoing or anticipated antiangiogenic treatment Current Diagnostic and Statistical Manual (DSM) IV-defined depressive disorder Uncontrolled glaucoma, diabetic retinopathy, corneal dystrophy, or anticipated cataract surgery Cognitive impairment on an abbreviated version of the Mini-Mental Status Examination that omits vision-dependent items.
Patient characteristics	Demographic Characteristics, Mean (SD) or N (%) Age (y) BA + LVR (n = 96): 85.2 (6.6) ST + LVR (n = 92): 82.7 (6.9)

Bibliographic reference	Rovner,B.W., Casten,R.J., Hegel,M.T., Massof,R.W., Leiby,B.E., Ho,A.C., Tasman,W.S., 20150326, Low vision depression prevention trial in age-related macular degeneration: a randomized clinical trial, Ophthalmology, 121, 2204-2211, 2014
	<p>Sex (female)</p> <p>BA + LVR (n = 96): 70 (72.9%)</p> <p>ST + LVR (n = 92): 62 (67.4%)</p> <p>Chronic disease score</p> <p>BA + LVR (n = 96): 5.5 (3.0)</p> <p>ST + LVR (n = 92): 5.8 (2.8)</p> <p>Medical Outcomes Study</p> <p>BA + LVR (n = 96): 13.0 (4.3)</p> <p>ST + LVR (n = 92): 12.9 (4.0)</p> <p>Best eye distance acuity (logMAR)</p> <p>BA + LVR (n = 96): 0.68 (0.40)</p> <p>ST + LVR (n = 92): 0.65 (0.34)</p> <p>Worse eye distance acuity (logMAR)</p> <p>BA + LVR (n = 96): 1.36 (0.66)</p> <p>ST + LVR (n = 92): 1.39 (0.65)</p> <p>Previous anti-VEGF treatment</p> <p>BA + LVR (n = 96): 49 (51.0%)</p> <p>ST + LVR (n = 92): 42 (45.7%)</p> <p>Depressive symptoms (PHQ-9)</p> <p>BA + LVR (n = 96): 5.5 (2.5)</p> <p>ST + LVR (n = 92): 5.6 (2.2)</p> <p>Study did not report the following important baseline characteristics:</p> <p>Ethnic group</p> <p>Visual acuity</p> <p>Comorbidities affecting the eye</p>

<b>Bibliographic reference</b>	<b>Rovner,B.W., Casten,R.J., Hegel,M.T., Massof,R.W., Leiby,B.E., Ho,A.C., Tasman,W.S., 20150326, Low vision depression prevention trial in age-related macular degeneration: a randomized clinical trial, Ophthalmology, 121, 2204-2211, 2014</b>
	Time since diagnosis of AMD Time since visual impairment due to AMD Disease stage
Details	<p>Follow up was 4 months</p> <p>Outcomes</p> <p>Depression—DSM-IV diagnosis of major or minor depression based on the Patient Health Questionnaire-9 (PHQ-9).<sup>13</sup> The PHQ-9 includes the 9 criteria that define DSM-IV diagnoses of depression and is valid in low-vision patients.</p> <p>Self-reported Functional Vision—Activities Inventory and the National Eye Institute Vision Function Questionnaire-25 (NEI-VFQ) near and distance activities sub-scales. The Activities Inventory measures the ability to achieve general vision-dependent activity goals, and perform specific vision-dependent cognitive and motor tasks. The NEI-VFQ rates difficulty performing daily activities. Standardized scores range from 0 to 100, with higher scores indicating better function.</p> <p>Vision-Related Quality of Life—a latent variable comprised of the NEI-VFQ social functioning, mental health, role difficulties, and dependency subscales. Standardized scores range from 0 to 100 with higher scores indicating better life quality.</p> <p>Vision Status—Standardized measurement of distance and near visual acuity, contrast sensitivity, and the size and location of central scotomas.</p> <p>Physical Health Status—The Chronic Disease Score and the Medical Outcomes Study-6 (MOS-6). The Chronic Disease Score yields a weighted score based on medication use that reflects severity of medical comorbidity. The MOS-6 yields a global index of self-rated physical and mental health. Higher scores on both scales reflect worse health status.</p> <p>Personality—The Revised Neuroticism, Extroversion, Openness Five Factor Inventory was used to assess the personality traits of neuroticism, conscientiousness, and openness to experience. Higher scores reflect higher standing on a given trait.</p> <p>Behavioural Activation for Depression Scale— Measures engagement in social and occupational activities. Its 4 subscales tap activation, avoidance/rumination, work/school impairment, and social impairment. Scores range from 0 to 42; higher scores reflect worse functioning.</p> <p>Device Use—Subjects rated their frequency of use of various low vision aids (e.g., task lighting) and devices (e.g., magnifiers) to improve visual ability</p>
Interventions	Low Vision Optometry - one of 5 community-based low vision optometrists evaluated and treated all subjects before randomization. The 2 clinic visits included assessment of vision function (e.g., visual acuity, refraction), and prescribing devices and providing instruction on their use. The study provided \$350 to all subjects to purchase a basic set of optical

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	<p>devices. After these visits, subjects were randomized to BA, which was delivered by 1 of 5 occupational therapists, or ST, which was delivered by 1 of 3 masters-level therapists (e.g., social workers).</p> <p>BA+LVR - the occupational therapists delivered 6 in-home, 1-hour BA sessions over 8 weeks. Treatment emphasized the link between action, mood, and mastery, and promoted self-efficacy and social connection as ways to improve mood and function and counter self-defeating behaviours (e.g., social withdrawal). The occupational therapist suggested environmental modifications to improve function and, with the subject, developed action plans to accomplish valued personal and functional goals. The action plans drew on rehabilitation principles (e.g., breaking down tasks into manageable steps), were integrated into daily routines, and focused on increasing social activities and reducing vision-related task difficulty. The latter was accomplished by increasing magnification, improving lighting, highlighting objects with high-contrast tape, and simplifying routines.</p> <p>ST+LVR - supportive therapy therapists delivered 6 in-home, 1-hour sessions over 8 weeks to facilitate discussion of illness, disability, and vision loss. Treatment facilitated personal expression about vision loss and disability and, in this trial, controlled for the nonspecific effects of attention.</p>
Results	<p>Incident depressive disorder at 4 months follow up, n (%)</p> <p>BA + LVR (n = 96): 11 (12.6)</p> <p>ST + LVR (n = 92): 18 (23.7)</p> <p>Adjusted Relative Risk (CI) of incidence depressive disorder at 4 months: 0.51 (0.27–0.97)*</p> <p>Adjusted for: vision severity stratum, and baseline neuroticism, Patient Health Questionnaire-9, and Medical Outcomes Study-6 scores.</p>
Overall Risk of Bias	<p>Risk of bias assessed using the Cochrane risk of bias tool</p> <p>Overall risk of bias: Moderate</p> <p>Other information: None</p> <p>Was the allocation sequence adequately generated? Yes</p> <p>Was allocation adequately concealed? Yes</p> <p>Was knowledge of the allocated intervention adequately prevented during the study? No (investigator "single" blind)</p> <p>Were incomplete outcome data adequately addressed? Yes</p> <p>Are reports of the study free of suggestion of selective outcome reporting? Yes</p>



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	Was the study apparently free of other problems that could put it at a high risk of bias? Single masked study. Attrition: There were no differences between enrolled subjects and eligible patients who declined participation with regard to age, sex, or visual acuity. Loss to follow up was moderate and anticipated (10%). Those lost to follow up had higher baseline Chronic Disease Scores (i.e., worse medical status) and worse visual acuity than retained subjects but did not differ in PHQ-9 or MOS-6 scores. Groups did not appear to have received different treatment other than the intervention of interest. Selection bias: The study did not report baseline characteristics for: Ethnic group, Visual acuity, Comorbidities affecting the eye, Time since diagnosis of AMD, Time since visual impairment due to AMD and Disease stage. BA+LVR subjects were somewhat older and more often married, The BA+LVR subjects used a greater number of low vision devices+ than ST+LVR subjects (this could be a confounder or a treatment effect).