Chapter 8: Stepped care for depression and anxiety in visually impaired older adults: multicentre randomised controlled effectiveness trial

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Abstract

Objective
To compare the effectiveness of a stepped care programme with usual care in visually impaired older adults with subthreshold depression and/or anxiety.

Methods
A single-masked multicentre international randomised controlled trial in two parallel groups was performed in 17 locations of three outpatient low vision rehabilitation organisations in the Netherlands and Belgium. A total of 265 visually impaired patients (aged ≥50 years) from low vision rehabilitation organisations with subthreshold depression and/or anxiety were randomly assigned in a 1:1 ratio with stratification (by trial centre) to either the stepped care programme plus usual care (n=131) or usual care only (n=134). A population-specific stepped care programme was offered containing: 1) watchful waiting, 2) cognitive behavioural therapy-based guided self-help, 3) problem solving treatment, and 4) referral to the general practitioner, delivered by supervised occupational therapists, social workers and psychologists from low vision rehabilitation organisations. The primary outcome was the 24-month cumulative incidence (seven measurements) of major depressive, dysthymic and/or anxiety disorders (panic disorder, agoraphobia, social phobia and generalized anxiety disorder) according to the DSM-IV criteria, measured with the Mini International Neuropsychiatric Interview. Secondary outcomes were change in symptoms of depression and anxiety, vision-related quality of life, health-related quality of life, and adaptation to vision loss over time until 24 months follow-up.

Results
After 24 months 62 participants from the usual care group (46%) and 38 participants from the stepped care group (29%) had developed a depressive and/or anxiety disorder (absolute difference 17%; 95% confidence interval CI 13 to 22). The intervention significantly reduced the incidence of the disorders (relative risk 0.63; 95% CI 0.57 to 0.69), even if time to the event was taken into account (adjusted hazard ratio 0.57; 95% CI 0.35 to 0.93). The number needed to treat was 5.8. In addition, a significant improvement was found for symptoms of depression (group difference -0.57, 95% CI -1.04 to -0.10), symptoms of anxiety (group difference -0.21, 95% CI -0.41 to -0.01) and vision-related quality of life (group difference 3.81, 95% CI 0.65 to 6.96) in favour of stepped care.

Conclusions
Stepped care seems to be a promising way to deal with depression and anxiety in visually impaired older adults. This approach could lead to standardised strategies for the treatment of depression and anxiety in visually impaired older adults.

Introduction
Impaired vision is an important cause of age-related disability; 285 million people globally are visually impaired, of whom 65% are aged ≥50 years.1 Depression and anxiety are common health problems in visually impaired older adults. About one-third experience subthreshold depression and/or anxiety (indicating clinically significant symptoms, but no actual disorder).2,3 About 7% are diagnosed with an anxiety disorder and 5-7% with a major depressive disorder according to the DSM-IV.4-6 These percentages are substantially higher than the prevalence in the general elderly population.7-9 Both disorders can have a detrimental impact on visually impaired older adults, leading to increased vision-specific disability, decreased quality of life, a decline in health status, and even mortality.7,10-11 However, care providers underestimate the negative effects of vision loss on mental health, standard procedures are missing, and patients often do not perceive a need for professional mental health services.7,10-12 Hence, detection of depression and anxiety is poor and treatment is often lacking.

Systematic reviews show that some studies have found effective psychological interventions, i.e. self-management programmes and problem-solving treatment (PST), to reduce depression in visually impaired older adults.10-14 These reviews suggest that psychological interventions can be incorporated into low vision rehabilitation, because functional ability and depression are closely related in this group. In addition, effects of psychological interventions have only been studied up to six months,14 while longer-term efforts to monitor and prevent depression and anxiety may be needed. Visually impaired older adults are likely to face further physical decline over time (eye diseases are often degenerative), which can lead to an increased risk of depression and anxiety.10

Several studies outside the field of low vision found that stepped care service delivery models, designed to delay or prevent the onset of depression and anxiety in persons who show early symptoms, can be effective.15 Stepped care aims to meet the long-term disease management needs of patients and maximise the effectiveness and efficiency of resource allocation. Subsequent treatment components are offered by order of intensity, i.e. patients start with low-intensity interventions and only move on to higher-intensity interventions when a sufficient response is lacking. Progress is monitored throughout the entire process.16 Current multidisciplinary guidelines for mental healthcare in the Netherlands and the National Institute for Health and Care Excellence (NICE) in the United Kingdom, recommend using a stepped care model to address depression in older adults.17-19 However, stepped care has not been investigated in chronic visually impaired older adults, who experience specific difficulty in adjusting to their disability. Taking into account the high prevalence of depression and anxiety in this population and the possibilities of a long-term preventive approach, the present study aimed to investigate the effectiveness of a population specific stepped care programme to prevent the onset of major depressive, dysthymic and anxiety disorders. In addition, the effects on reducing symptoms of depression and anxiety, and improve adaptation to vision loss and quality of life were determined. It was hypothesised that stepped care, incorporated in low vision rehabilitation care, would be more effective than usual care alone.

Methods

Study design
This study used a single-masked international multicentre randomised controlled trial (RCT) design, exactly as described in the original protocol.20 Participants were individually randomised in the ratio 1:1 to one of two parallel groups i.e. to usual care or stepped care plus usual care.
Participants
Between July 2012 and April 2013, a total of 3,000 patients aged ≥ 50 years from outpatient low vision rehabilitation organisations in the Netherlands and Belgium were contacted by letter and telephone and asked to participate. Of these, 914 provided written informed consent (response rate 30%). Participants were allowed to withdraw their consent for any reason at any time during the study. Baseline interviews with responders were performed to determine eligibility.

The low vision rehabilitation organisations follow the World Health Organisation (WHO) criteria for eligibility, which are described in the Dutch guideline ‘Vision disorders, rehabilitation and referral’. This guideline dictates that all patients should have a decimal visual acuity of ≤0.3 and/or a visual field of ≤30 degrees around the central point of fixation and/or an evident help request for which options in regular ophthalmic practice are not adequate, such as contrast sensitivity or glare. Additional inclusion criteria were: a) having subthreshold depression and/or anxiety; i.e. a score of ≥8 on the Hospital Anxiety and Depression Scale-Anxiety subscale (HADS-A)5,12, and/or ≥16 on the Centre for Epidemiologic Studies Depression scale (CES-D)12,23; b) not meeting the diagnostic criteria of a major depressive, dysthymic and/or anxiety disorder according to the DSM-IV (measured with the Mini International Neuropsychiatric Interview [MINI])14,25; c) being able to speak the Dutch language adequately; and d) not being severely cognitively impaired (measured with the Six-item screener, a short version of the Mini Mental State Examination; MMSE)14. Additional details on inclusion criteria and protocol design are described elsewhere.14

Patient involvement
Patients (n=8) from low vision rehabilitation organisations were involved in the development and implementation of the stepped care programme based on two focus group meetings in the Netherlands and Belgium. Patients were not involved in determining study conduct, recruitment and design. The burden of the intervention and participation in the study in general was assessed by a panel of patient representatives which was assigned by the funding agency. The burden of the intervention was not assessed as such by participating patients, but satisfaction with the intervention was. Results of the study will be disseminated by letter to all participants by the end of the study.

Randomisation and masking
A pre-specified power calculation was based on the study of van ‘t Veer et al. (2009),12 who found the proportion of people developing a disorder to be 0.4 in the control group and 0.2 in the intervention with a relative risk of 0.5, leading to an effect size of 2*arcsinus(√0.2)−2*arcsinus(√0.4)=0.44. In addition, we used α≤0.05 (two-sided), power 0.85, drop-out rate 20%, and/or ≥16 on the CES-D) they could move on to the next step. A score below the cut-off point indicated that the following step of the programme. Therefore, not all patients of the stepped care group completed all steps of the intervention. Patients were seen at the rehabilitation centre or at home, based on the patient’s preference. Patients in both the stepped care and usual care group who developed a major depressive, dysthymic and/or anxiety disorder, were directly referred to their GP to discuss further treatment. Usual care in both the treatment and control group included outpatient low vision rehabilitation care and/or care that was provided by other healthcare providers.

The programme was altered and tailored to

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The primary outcome measure of this study was the incidence of major depressive, dysthymic and/or anxiety disorders (panic disorder, agoraphobia, social phobia and/or generalized anxiety disorder) according to the DSM-IV, for which the Dutch MINI Plus (5.0.0), developed in clinician-rated format, was used at baseline, and at 3, 6, 9, 12, 18 and 24 months in both the treatment and control group. The MINI is a brief, structured interview developed to diagnose psychiatric disorders according to DSM-IV criteria. It is considered a valid and reliable tool to define mental disorders based on a 20-minute telephone interview.\textsuperscript{24,25} The MINI shows moderate to high kappa coefficients for all diagnoses, except for generalized anxiety disorder for which the kappa is just below 0.5.\textsuperscript{24} Although a dysthymic disorder requires a depressed mood for 2 years (not interrupted by more than two months at a time), it was included in the outcome measure, because participants who were not diagnosed with a dysthymic disorder at one time point (e.g. they were only experiencing a depressed mood for the last 1.5 years) could be diagnosed with this disorder by the next time point. History of major depressive, dysthymic and panic disorder at baseline were also determined with the MINI.

Secondary outcome measures were symptoms of depression and anxiety measured with the CES-D and HADS-A at baseline, and at 3, 6, 9, 12, 18 and 24 months. The CES-D is a 20-item scale with a total score ranging from 0-60 and a cut-off score for subthreshold depression and/or anxiety of ≥16. It is a widely used scale and considered a valid and reliable instrument to measure both depression and anxiety symptomatology in older adults.\textsuperscript{22,23} The HADS-A was used to measure symptoms of anxiety. The HADS-A has seven items, with a total score ranging from 0-21 and a cut-off score for subthreshold anxiety of ≥8. The reliability of the HADS-A is reported to be ‘good to very good’ in older adults.\textsuperscript{22,23} In addition, vision-related quality of life was measured with the Low Vision Quality of Life Questionnaire (LVQOL, with 21 questions on a 6-point Likert scale, measuring the disability suffered by patients in daily life)\textsuperscript{32,33} and adaptation to vision loss was measured with the Adaptation to Vision Loss (AVL) scale (adapted from the AVL-12, with 9 questions on a 4-point Likert scale, measuring intra and interpersonal acceptance of vision loss) at baseline, after 12 and 24 months. Psychometric properties of these questionnaires with item response theory (IRT) models. No evidence of multidimensionality, local dependence or differential item functioning (DIF) was found and all scales showed good fit to the model (i.e. graded-response model), except the HADS-A. Three items from the LVQOL were deleted to resolve local dependence, leading to the unidimensional LVQOL-18.

Health-related quality of life was measured at baseline after 12 and 24 months with the EuroQol-5 Dimensions (EQ-5D, which consists of five dimensions of functional impairment: mobility, self-care, usual activities, pain/discomfort and depression/anxiety).\textsuperscript{34} Utility scores based on the Dutch tariff were used, where 1 denotes full health and 0 means a health state comparable to death (range -0.58 to 1, where negative utilities are valued as worse than death).\textsuperscript{23}

For the process evaluation, first, compliance with treatment in step two and three of the programme was measured based on the number of patients who rejected the intervention and the number and duration of appointments. Second, therapist adherence to the PST protocol was reviewed based on audiotapes of a random selection of PST sessions (n=13). Third, adoption of the interventions was determined based on therapists’ experiences, measured with two questions: 1) ‘Are you satisfied with the results of the intervention?’, 2) ‘Do you think the intervention suited the needs of the patient?’, and patient-evaluation of the services, measured with the Dutch Mental Healthcare (MH) thermometer of satisfaction: a widely used 20-item questionnaire.\textsuperscript{22}

Usual care was measured at 6, 12, 18 and 24 months with the Trimbos/IMTA questionnaire for Costs associated with Psychiatric Illness (TicP).\textsuperscript{31} This questionnaire measured self-reported healthcare utilisation based on the number of contacts with a GP, company physician, medical specialist, physiotherapist or occupational therapist, social worker, psychologist or psychiatrist, alternative healer, homecare, guided group-based peer support, hospitalisation and use of medication in the past six months.\textsuperscript{35} Received mental health services in three months before the start of the study was determined at baseline with the Perceived Need for Care Questionnaire (PNCQ), measuring 1) received information about mental illness and treatment possibilities, 2) practical support, 3) skills training, 4) counselling/therapy, and 5) medication.\textsuperscript{35}
Decimal visual acuity was retrieved from patient files at the low vision rehabilitation centres; missing values (n=22) were supplemented with estimates of visual acuity provided by self-report based on recent ophthalmic diagnostics. To enable meaningful computations, these values were transformed to logMAR values ($-\log_{10}$ visual acuity) where a visual acuity of 0.00-0.29 represents normal vision, 0.30-0.51 mild vision loss, and 0.52-2.00 low vision or blindness.

Patients were asked about comorbidity based on eight major condition groups: peripheral arterial disease; asthma or chronic obstructive pulmonary disease; diabetes mellitus; osteoarthritis and rheumatoid arthritis; cerebrovascular accident or stroke; cardiac disease; cancer; and other chronic conditions. Compared to GP information, the accuracy of the self-reports of these diseases was shown to be adequate and independent of cognitive impairment.

**Table 1. Uptake of the different steps of the stepped care programme in the intervention group (n=131) during 12 months**

<table>
<thead>
<tr>
<th>Treatment components</th>
<th>0-3 months (n=131)</th>
<th>3-6 months (n=124)</th>
<th>6-9 months (n=108)</th>
<th>9-12 months (n=98)</th>
<th>Total (0-12 months) (n=131)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Watchful waiting (n (%))</td>
<td>131 (100%)</td>
<td>131 (100%)</td>
<td>131 (100%)</td>
<td>131 (100%)</td>
<td>131 (100%)</td>
</tr>
<tr>
<td>2. Guided self-help (n (%))</td>
<td>58 (47%)</td>
<td>14 (13%)</td>
<td>1 (1%)</td>
<td>73 (56%)</td>
<td>73 (56%)</td>
</tr>
<tr>
<td>3. PST (n (%))</td>
<td>18 (17%)</td>
<td>11 (11%)</td>
<td>29 (22%)</td>
<td>29 (22%)</td>
<td></td>
</tr>
<tr>
<td>4. Referral GP (n (%))</td>
<td>7 (7%)</td>
<td>7 (5%)</td>
<td>7 (5%)</td>
<td>7 (5%)</td>
<td></td>
</tr>
</tbody>
</table>

PST problem solving treatment; GP general practitioner

Results

**Participant flow**

Non-responders (n=2086) were significantly older than responders (n=914, mean difference 4.6 years, p<0.001), no significant difference in gender was found. Baseline interviews resulted in the exclusion of 519 responders who had no depression/anxiety symptoms, 124 who had a depressive/anxiety disorder and 6 who were cognitively impaired. The remaining 265 eligible participants were randomised to either the stepped care group (n=131) or the usual care group (n=134). Of these, 91 participants were lost to follow-up after 24 months (34%); 45 in the stepped care group and 46 in the usual care group (Figure 2). Those who dropped-out of the study were significantly older and more often lived in a nursing home than those who were not lost to follow-up (p<0.05). The most common reasons for loss to follow-up were: i) mortality (16% of stepped care and 24% of the usual care group), ii) physically or mentally not able to continue (18% of stepped care and 22% of usual care group), and iii) too great a burden to continue (18% of stepped care and 17% of usual care group).

Of the stepped care group, all participants received a period of watchful waiting, 56% received guided self-help, 22% received PST, and 5% were referred to their GP (Table 1). Patients who did not move on to the next step of the programme either no longer had subthreshold symptoms of depression and/or anxiety, or developed a full-blown depression and/or anxiety disorder and were immediately referred to their GP. No significant difference was found between the stepped care and usual care group in baseline patient characteristics and healthcare utilisation, except for education level (p<0.05, Table 2).
### Chapter 8 Effectiveness of stepped care: RCT

<table>
<thead>
<tr>
<th>Patient characteristics measured at baseline</th>
<th>Intervention group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female gender (n %)</td>
<td>91 (70%)</td>
<td>94 (70%)</td>
</tr>
<tr>
<td>Age in years, range [50-98] (mean (SD))</td>
<td>72.4 (12.5)</td>
<td>74.9 (11.9)</td>
</tr>
<tr>
<td>Education in years, range [0-16] (mean (SD))</td>
<td>10.4 (3.8)</td>
<td>9.3 (3.4)</td>
</tr>
<tr>
<td>Nationality (n %)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dutch</td>
<td>116 (89%)</td>
<td>117 (87%)</td>
</tr>
<tr>
<td>Belgian</td>
<td>14 (11%)</td>
<td>16 (12%)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (1%)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Living situation (independent) (n %)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Usually enough money</td>
<td>61 (47%)</td>
<td>62 (46%)</td>
</tr>
<tr>
<td>Just enough money</td>
<td>55 (42%)</td>
<td>57 (43%)</td>
</tr>
<tr>
<td>Not enough money</td>
<td>10 (8%)</td>
<td>15 (11%)</td>
</tr>
<tr>
<td>Income (n %)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Macular degeneration</td>
<td>62 (47%)</td>
<td>60 (45%)</td>
</tr>
<tr>
<td>Glaucoma</td>
<td>26 (20%)</td>
<td>19 (14%)</td>
</tr>
<tr>
<td>Cataract</td>
<td>26 (20%)</td>
<td>19 (14%)</td>
</tr>
<tr>
<td>Diabetic retinopathy</td>
<td>5 (4%)</td>
<td>4 (3%)</td>
</tr>
<tr>
<td>Cerebral haemorrhage</td>
<td>5 (4%)</td>
<td>10 (8%)</td>
</tr>
<tr>
<td>Other</td>
<td>45 (34%)</td>
<td>60 (45%)</td>
</tr>
<tr>
<td>Time of onset of visual loss in years (median [25-75% percentiles])</td>
<td>8 [3-19]</td>
<td>8 [3-16]</td>
</tr>
<tr>
<td>LogMAR visual acuity (n %)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal visual acuity*</td>
<td>9 (7%)</td>
<td>15 (11%)</td>
</tr>
<tr>
<td>Mild vision loss</td>
<td>24 (18%)</td>
<td>23 (17%)</td>
</tr>
<tr>
<td>Low vision / blindness</td>
<td>86 (66%)</td>
<td>86 (64%)</td>
</tr>
<tr>
<td>Comorbidity range [0-5] (mean (SD))</td>
<td>1.1 (1.2)</td>
<td>1.2 (1.2)</td>
</tr>
<tr>
<td>History of major depressive disorder (n %)</td>
<td>30 (23%)</td>
<td>25 (19%)</td>
</tr>
<tr>
<td>History of dysthymic disorder (n %)</td>
<td>4 (3%)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>History of panic disorder (n %)</td>
<td>8 (6%)</td>
<td>8 (6%)</td>
</tr>
<tr>
<td>Mental health services received in three months before baseline (n %)</td>
<td>Information 14 (11%)</td>
<td>13 (10%)</td>
</tr>
<tr>
<td>Practical support</td>
<td>38 (29%)</td>
<td>34 (25%)</td>
</tr>
<tr>
<td>Skills training</td>
<td>5 (4%)</td>
<td>4 (3%)</td>
</tr>
<tr>
<td>Counselling/therapy</td>
<td>20 (15%)</td>
<td>17 (13%)</td>
</tr>
<tr>
<td>Referral to specialist</td>
<td>5 (4%)</td>
<td>4 (3%)</td>
</tr>
<tr>
<td>Medication</td>
<td>17 (13%)</td>
<td>28 (21%)</td>
</tr>
</tbody>
</table>

Means and standard deviations (SD) are reported for continuous variables, median and 25-75% percentiles are provided when the variable has an asymmetric distribution.

* These participants have a visual field of ≤30 degrees and/or an evident help request for which options in regular ophthalmic practice are not adequate, such as contrast sensitivity or glare.

SD standard deviation
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Effectiveness

Of the 131 participants in the stepped care group, 38 (29%) developed a major depressive, dysthymic and/or anxiety disorder versus 62 of the 134 participants (46%) in the usual care group during the 24-month follow-up. The absolute difference was 17% (95% confidence interval (CI) 13 to 21). The stepped care programme significantly reduced the incidence of depressive and anxiety disorders with a relative risk of 0.63 (95% CI 0.45 to 0.87, \( p < 0.01 \)). The number needed to treat (as an inverse of the absolute risk difference, 1/0.17) was 5.8 (95% CI 3.5 to 17.3), indicating the average number of patients who needed to be treated to prevent one additional depressive or anxiety disorder. Of the 38 patients who developed a disorder in the stepped care group 19 had a history of major depressive, dysthymic and/or panic disorder (50%), compared to 18 of the 62 patients in the control group (29%). This difference was statistically significant (\( \chi^2 = 4.4, p = 0.04 \)). Mental health services used in the past for people who developed a disorder during this trial were not statistically different for the stepped care and usual care group.

The Kaplan Meier curve and the Log-rank test showed a significant difference in time to the onset of a depressive and/or anxiety disorder between the stepped care and usual care group (Figure 3, \( \chi^2 = 8.2; p = 0.004 \)). Cox-regression analysis showed a crude hazard ratio of 0.59 (95% CI 0.38 to 0.91, \( p = 0.02 \)) and an adjusted hazard ratio of 0.57 (95% CI 0.35 to 0.93, \( p = 0.02 \), adjusted for centre and baseline patient characteristics described in Table 2). The proportional hazard assumption was met.

Significant intervention effects were observed after 24 months for the CES-D (group difference -0.57, 95% CI -1.04 to -0.10, \( p = 0.02 \)), the HADS-A (group difference -0.21, 95% CI -0.41 to -0.01, \( p = 0.04 \)) and the LVQOL-18 (group difference 3.81, 95% CI 0.65 to 6.96, \( p = 0.02 \)) in favour of stepped care. However, no significant intervention effects were found for the AVL-9 (group difference 0.19, 95% CI -1.13 to 1.51, \( p = 0.8 \)) and the EQ-5D (group difference 0.02, 95% CI -0.05 to 0.09, \( p = 0.6 \)).

Observed mean summary scores of the secondary outcomes per measurement for the stepped care and usual care group are presented in Table 3.

**FIGURE 1.** Flow diagram of study participants

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**Enrollment**

Invited by letter and telephone (n=3,000)

Screened for eligibility (n=914)

Randomised (n=265)

Excluded (n=649)

• no depression/anxiety symptoms (n=519)
• depressive and/or anxiety disorder (n=124)
• cognitively impaired (n=6)

Non-response (n=2,086)

Allocated to stepped care (n = 131)

Allocated to usual care (n = 134)

Dropped-out (n=7)

• Refused (n=5)
• Died (n=2)

No show (n=5)

• Refused (n=11)
• Died (n=1)

Follow-up 3 months

• Refused (n=1)

Follow-up 6 months

• Refused (n=4)

Follow-up 9 months

• Refused (n=6)

Follow-up 12 months

• Cognition (n=1)

Follow-up 18 months

• Cognition (n=2)

Follow-up 24 months

• Cognition (n=1)

Follow-up (n=103)

Follow-up (n=106)

Follow-up (n=98)

Follow-up (n=102)

Follow-up (n=85)

Follow-up (n=95)

Follow-up (n=86)

Follow-up (n=88)

Follow-up (n=108)

Follow-up (n=109)

Follow-up (n=124)

Follow-up (n=122)

Follow-up (n=107)

Follow-up (n=120)

Follow-up (n=109)

Follow-up (n=108)

Follow-up (n=107)

Follow-up (n=106)

Follow-up (n=105)

Follow-up (n=104)

Follow-up (n=103)

Follow-up (n=102)

Follow-up (n=101)

Follow-up (n=100)

Follow-up (n=99)

Follow-up (n=98)

Follow-up (n=97)

Follow-up (n=96)

Follow-up (n=95)

Follow-up (n=94)

Follow-up (n=93)

Follow-up (n=92)

Follow-up (n=91)

Follow-up (n=90)

Follow-up (n=89)

Follow-up (n=88)

Follow-up (n=87)

Follow-up (n=86)

Follow-up (n=85)

Follow-up (n=84)

Follow-up (n=83)

Follow-up (n=82)

Follow-up (n=81)

Follow-up (n=80)

Follow-up (n=79)

Follow-up (n=78)

Follow-up (n=77)

Follow-up (n=76)

Follow-up (n=75)

Follow-up (n=74)

Follow-up (n=73)

Follow-up (n=72)

Follow-up (n=71)

Follow-up (n=70)

Follow-up (n=69)

Follow-up (n=68)

Follow-up (n=67)

Follow-up (n=66)

Follow-up (n=65)

Follow-up (n=64)

Follow-up (n=63)

Follow-up (n=62)

Follow-up (n=61)

Follow-up (n=60)

Follow-up (n=59)

Follow-up (n=58)

Follow-up (n=57)

Follow-up (n=56)

Follow-up (n=55)

Follow-up (n=54)

Follow-up (n=53)

Follow-up (n=52)

Follow-up (n=51)

Follow-up (n=50)

Follow-up (n=49)

Follow-up (n=48)

Follow-up (n=47)

Follow-up (n=46)

Follow-up (n=45)

Follow-up (n=44)

Follow-up (n=43)

Follow-up (n=42)

Follow-up (n=41)

Follow-up (n=40)

Follow-up (n=39)

Follow-up (n=38)

Follow-up (n=37)

Follow-up (n=36)

Follow-up (n=35)

Follow-up (n=34)

Follow-up (n=33)

Follow-up (n=32)

Follow-up (n=31)

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Follow-up (n=28)

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Follow-up (n=26)

Follow-up (n=25)

Follow-up (n=24)

Follow-up (n=23)

Follow-up (n=22)

Follow-up (n=21)

Follow-up (n=20)

Follow-up (n=19)

Follow-up (n=18)

Follow-up (n=17)

Follow-up (n=16)

Follow-up (n=15)

Follow-up (n=14)

Follow-up (n=13)

Follow-up (n=12)

Follow-up (n=11)

Follow-up (n=10)

Follow-up (n=9)

Follow-up (n=8)

Follow-up (n=7)

Follow-up (n=6)

Follow-up (n=5)

Follow-up (n=4)

Follow-up (n=3)

Follow-up (n=2)

Follow-up (n=1)

Follow-up (n=0)

Complete data over time (n=131)

Complete data over time (n=134)
### Chapter 8

**TABLE 3.** Secondary outcomes at baseline, 3, 6, 9, 12, 24 months for the intervention (n=131) and control group (n=134)

<table>
<thead>
<tr>
<th>Outcomes (mean (SD))</th>
<th>baseline</th>
<th>3 months</th>
<th>6 months</th>
<th>9 months</th>
<th>12 months</th>
<th>18 months</th>
<th>24 months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intervention group (n=131)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptoms of depression (CES-D)</td>
<td>21.2 (6.6)</td>
<td>17.5 (9.3)</td>
<td>16.4 (9.3)</td>
<td>15.2 (9.7)</td>
<td>15.1 (9.4)</td>
<td>15.2 (9.4)</td>
<td>15.7 (10.9)</td>
</tr>
<tr>
<td>Symptoms of anxiety (HADS-A)</td>
<td>7.1 (4.1)</td>
<td>5.8 (4.1)</td>
<td>5.4 (4.0)</td>
<td>5.0 (4.0)</td>
<td>5.1 (4.4)</td>
<td>5.9 (3.8)</td>
<td>5.6 (4.6)</td>
</tr>
<tr>
<td>Vision-related QoL (LVQOL-18)</td>
<td>42.6 (13.2)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>41.2 (12.6)</td>
<td>-</td>
<td>42.1 (14.2)</td>
</tr>
<tr>
<td>Adaptation to vision loss (AVL-9)</td>
<td>14.1 (5.7)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>14.6 (5.9)</td>
<td>-</td>
<td>14.5 (6.4)</td>
</tr>
<tr>
<td>Health-related QoL (EQ-5D)</td>
<td>0.7 (0.3)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>0.6 (0.3)</td>
<td>-</td>
<td>0.7 (0.3)</td>
</tr>
<tr>
<td><strong>Control group (n=134)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
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<td>17.5 (8.4)</td>
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<td>17.7 (9.4)</td>
<td>17.7 (9.2)</td>
</tr>
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<td>5.5 (3.6)</td>
<td>6.3 (3.6)</td>
<td>6.1 (4.3)</td>
<td>6.1 (4.2)</td>
<td>6.5 (3.9)</td>
<td>6.6 (4.3)</td>
</tr>
<tr>
<td>Vision-related QoL (LVQOL-18)</td>
<td>42.2 (14.5)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>44.3 (13.7)</td>
<td>-</td>
<td>40.8 (15.7)</td>
</tr>
<tr>
<td>Adaptation to vision loss (AVL-9)</td>
<td>13.6 (5.7)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>14.5 (5.5)</td>
<td>-</td>
<td>14.7 (5.7)</td>
</tr>
<tr>
<td>Health-related QoL (EQ-5D)</td>
<td>0.7 (0.2)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>0.6 (0.3)</td>
<td>-</td>
<td>0.7 (0.3)</td>
</tr>
</tbody>
</table>

MINI: Mini International Neuropsychiatric Interview; CES-D: Centre for Epidemiologic Studies Depression; HADS-A: Hospital Anxiety and Depression Scale-Anxiety; QoL: quality of life; LVQOL: Low Vision Quality of Life Questionnaire; AVL: Adaptation to Vision Loss; EQ-5D Euroqol-5 Dimensions
Process evaluation

Out of 73 patients who were eligible for guided self-help, six refused and twelve only partly received guided self-help. Out of 29 patients who were eligible for PST, five refused and four only partly received PST. Main reasons were: i) participants did not believe this kind of help was necessary (37%) and ii) it was too great a burden to follow the intervention (28%). In four cases, patients received more help with the self-help course than pre-determined, i.e. one patient received an additional face-to-face and telephone contact, and four patients received an additional telephone contact. On average 5.33 (range 2-11) PST sessions took place. In two patients, the therapist offered more support than the pre-determined maximum of seven PST sessions, i.e. one patient received 9 and another patient received 11 PST sessions. Audiotapes showed fidelity to the PST treatment protocol. However, in two cases PST steps could not be completed during one session, they were then finished in another session. Occupational therapists were satisfied with the result of the self-help course in 73% of the cases and thought the intervention suited the needs of patients in 71% of the cases. Social workers and psychologists were also frequently satisfied with the result (68%) and believed that PST suited the needs of patients (63%). Information on patient-evaluation of services is presented in Table 4. Lower satisfaction scores were not associated with developing depressive and/or anxiety disorders after 24-months follow-up (Mann Whitney U test, guided self-help, P=0.6; PST, P=0.7).

TABLE 4. Patient-evaluation of guided self-help (n=73) and problem solving treatment (n=29)

<table>
<thead>
<tr>
<th>Treatment components (n (%))</th>
<th>Guided self-help</th>
<th>Problem solving treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information and participation:</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>I received sufficient information about the method/step</td>
<td>52 (71%)</td>
<td>6 (8%)</td>
</tr>
<tr>
<td>I received sufficient information about the expected result</td>
<td>43 (59%)</td>
<td>22 (30%)</td>
</tr>
<tr>
<td>I helped determine treatment possibilities</td>
<td>55 (75%)</td>
<td>10 (14%)</td>
</tr>
<tr>
<td>Professional:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The professional had sufficient expertise</td>
<td>48 (66%)</td>
<td>6 (8%)</td>
</tr>
<tr>
<td>I sufficiently trusted the professional</td>
<td>53 (73%)</td>
<td>5 (7%)</td>
</tr>
<tr>
<td>The professional showed respect</td>
<td>51 (70%)</td>
<td>6 (8%)</td>
</tr>
<tr>
<td>Result of the treatment:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>This was the right approach for my problems</td>
<td>48 (66%)</td>
<td>17 (23%)</td>
</tr>
<tr>
<td>The treatment increased my feelings of control</td>
<td>45 (62%)</td>
<td>20 (27%)</td>
</tr>
<tr>
<td>My situation sufficiently improved based on this treatment</td>
<td>39 (53%)</td>
<td>21 (29%)</td>
</tr>
<tr>
<td>I am able to do more things that are important to me</td>
<td>35 (48%)</td>
<td>16 (22%)</td>
</tr>
<tr>
<td>I can cope better with situations that I previously had difficulty with</td>
<td>42 (58%)</td>
<td>18 (25%)</td>
</tr>
<tr>
<td>Satisfaction score, range [4-10] (mean [SD])</td>
<td>7.54 (1.20)</td>
<td>7.05 (1.00)</td>
</tr>
</tbody>
</table>

Discussion

This study shows that, compared to usual care, stepped care had a significant preventive effect on developing depressive and anxiety disorders in visually impaired older adults over a 2-year period (adjusted hazard ratio=0.57) and significantly reduced depression and anxiety symptoms and improved vision-related quality of life. These outcomes resemble those of another study showing a stepped care programme for older adults in the general population to be effective in preventing depressive and anxiety disorders (≥75 years). This is an important outcome considering the serious consequences of these disorders in visually impaired older adults and the previous absence of long-term treatment effects. Preventing these disorders will have a positive impact on many different aspects of patients’ lives and may lead to a reduction of societal costs (e.g. healthcare costs and productivity).

The present study combined treatment components and monitored patients during a 2-year period by offering support only when needed, based on elevated symptoms of depression and anxiety. In combination with usual low vision rehabilitation care, this seems to be a promising strategy to manage depression and anxiety in this population. It also confirms previous findings indicating that psychological services could be integrated in low vision rehabilitation care, which will increase accessibility of these services and enable professionals to combine expertise on depression and vision impairment. Notably, these results were established even though only a few patients required receiving all four steps of the programme and all patients were included in the analyses.

Still, many participants (38% of the total study population) developed a depressive and/or anxiety disorder during the course of this study. In the stepped care group half of these patients had a history of depressive/anxiety disorders as opposed to 29% of the controls, indicating that especially first episodes of these disorders were prevented by the stepped care programme. Therefore, the programme may be less suited for visually impaired patients with a history of major depressive and anxiety disorders. These participants might benefit from higher intensity psychological interventions or pharmacotherapy.

Strengths and limitations

This study has several strengths. It shows that investigating different protocol-driven treatment components, based on successful randomisation and single masking, is feasible in low vision psychological intervention studies. Drop-out rates were high but acceptable and treatment fidelity was largely maintained. The pragmatic design of the study greatly enhances the generalisability of the results, giving rise to widespread implementation within low vision rehabilitation care. In contrast to previous trials in the field of low vision, this study addressed both depression and anxiety, which is relevant considering the high comorbidity of these disorders, and investigated a long-term disease management model, during which support was only offered when needed based on elevated symptoms of depression and anxiety, to maximise effectiveness and efficiency. In addition, many patients were recognised as having subthreshold depression and/or anxiety or an actual disorder based on the screening and monitoring procedure, which otherwise may not have been identified. This highlights the need for such procedures within low vision care delivery models.

However, this study also has some limitations. First, it was not possible to assess the specific contributions of each individual step of the programme. Future studies might choose a dismantling approach; determining redundant treatment components. Second, selection bias may have occurred because patients who volunteered and were selected for this study may have differed from other eligible individuals, thereby reducing the generalisability of the outcomes. Responders were significantly younger than non-responders, and participants had less cognitive and physical problems and may, for instance, have had better access to healthcare and may have
been more motivated based on hope of personal gain. Third, both low vision staff and patients were unmasked, which could have led to some information bias, i.e. participants in the stepped care group might have had more attention on treatment outcomes, leading to an overestimation of the results. The low kappa coefficient for diagnosing generalized anxiety disorder with the MINI may have led to over- or underidentification of this disorder. In addition, not to overcomplicate interpretation of the secondary outcomes, effect estimates analysed with IRT models that are increasingly used in the field of ophthalmology, optometry and low vision were not reported here. With IRT models, the effect estimates were similarly significant, except for vision-related quality of life (data not shown). Finally, the drop-out rate was fairly high (34%). This was partly expected because we examined a fragile study population (elderly with a vision impairment and depression/anxiety) and because the follow-up period was longer than any previous psychological intervention study performed in the field of low vision (seven measurements in two years). Drop-out rates were not significantly different for the stepped care and control group, indicating that the intervention was equally acceptable as usual care. However, we do need to realise that offering psychological interventions in this fragile population is a challenge and that feasibility should have a high priority in future studies.

**Implications for practice and directions for future research**

Findings of the current study introduce possibilities for standard choices on screening, monitoring, treatment and referral trajectories to deal with depression and anxiety in visually impaired older adults. Patients with subthreshold symptoms can benefit from the (low intensity) psychological services offered in the stepped care programme that can be integrated in low vision rehabilitation care. In many patients only watchful waiting, in which problems are identified and briefly discussed, and the CBT-based guided self-help course were sufficient to reduce depressive and anxiety symptoms. These low intensity and low cost interventions may fairly easily be implemented in low vision rehabilitation care, because of their accessibility (i.e. people with vision impairment do not have to travel), focus on empowerment and low intensity of necessary resources (i.e. professional support).

In addition, screening and monitoring procedures should be incorporated in low vision rehabilitation care, since detection of depression and anxiety, especially in an early stage of the complaints, is poor. Professionals (even non-mental health staff) should be made aware of the high prevalence and recurrent nature of these conditions and patients should be stimulated to talk about it both at the start of rehabilitation (intake procedure) and during treatment, since eye diseases are often degenerative which may lead to depression and anxiety over time. Patients with a history of major depressive and anxiety disorders should be monitored carefully and offered higher intensity psychological interventions or pharmacotherapy, because they less often benefitted from the stepped care programme.

In a future study we will examine the costs and cost-effectiveness of the stepped care programme compared to usual care. This is highly relevant in a field in which patient numbers are vastly increasing (caused by demographic ageing in developed countries) and healthcare systems already benefitted from the stepped care programme.

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References


