Chapter 8:

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

Published as:
van der Aa HPA, van Rens GHMB, Comijs HC, Margrain TH, Gallindo-Garre F, Twisk JWR, van Nispen RMA. Stepped care for depression and anxiety in visually impaired older adults: multicentre randomised controlled effectiveness trial
BMJ 2015; 352:h6127. DOI: http://dx.doi.org/10.1136/bmj.h6127

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).[2-5] About 7% are diagnosed with an anxiety disorder and 5-7% with a major depressive disorder, according to the DSM-IV.[5-7] These percentages are substantially higher than the prevalence in the general elderly population.[8,9] 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.[4,10-12] 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.[10,13] 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,[10,14] 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.[15] 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.[16,17] 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.[18] 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'.[19] 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)[20,21] and/or ≥16 on the Centre for Epidemiologic Studies Depression scale (CES-D)[22-23]; 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))[24,25]; 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).[26] Additional details on inclusion criteria and protocol design are described elsewhere.[18]

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 2015.

Randomisation and masking

A pre-specified power calculation was based on the study of van 't Veer et al. (2009),[27] 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%, which showed that a minimum of 230 patients was needed (115 in each arm).[18] Since drop-out rates observed at the start of the trial were higher than expected, more patients were recruited (*n*=265). Patients were assigned to either usual care, or the stepped care programme in addition to usual care. A computerised random number generator was used to produce the allocation scheme. The scheme was based on blocks of two and stratified by 17 locations of three outpatient low vision rehabilitation organisations in the Netherlands and Belgium. Randomisation took place after the baseline measurement by an independent researcher. Patients were registered as being a participant of this study in their records at the rehabilitation centres. Only when guidance needed to be offered in step two or three of the programme, were the clinical staff directly informed by the independent researcher as to which patient to treat.

Data was collected from September 2012 to July 2015, during which seven measurements took place (at baseline, and at 3, 6, 9, 12, 18 and 24 months) by means of telephone interviews. These were performed at the VU University Medical Centre by masked research assistants, who were trained to diagnose depressive and anxiety disorders and follow a pre-specified protocol. At the outset of the study and at the start of each telephone interview participants were told not to divulge the nature of their treatment during the telephone interviews. We checked if masking was

maintained by asking research assistants to guess which treatment arm was offered. They were right in 38% of the cases, indicating that masking was effective. To minimise the possibility of data entry errors, the research assistants used specially designed data entry software (Blaise) to record all measurements. Due to the nature of the intervention, the participants and therapists could not be masked.

Intervention

The stepped care programme was based on a model similar to that previously used in the general elderly population and shown to be effective.[27,28] The programme was altered and tailored to the needs of people with vision impairment based on a focus group with social workers and psychologists from the low vision rehabilitation organisations (*n*=12) and two focus group meetings with patient representatives (*n*=8). Specific attention was given to the difficulty of adjusting to vision loss and the physical and psychological consequences of this impairment (e.g. bereavement, fatigue, psychosocial adjustment) that may lead to feelings of depression and anxiety. Exercises and examples were altered and added based on direct input of patients and professionals. Specific attention was also given to the manner in which the programme was offered (e.g. audio and Braille version of written documents). Additional information on programme development is provided elsewhere.[18]

The final programme contained four consecutive steps that took about three months each: 1) watchful waiting, 2) cognitive behavioural therapy-based guided self-help, 3) PST, and 4) referral to the general practitioner (GP, Figure 1). All treatments were offered individually. Only when patients still had elevated symptoms of depression and/or anxiety (score of ≥8 on the HADS-A and/or ≥16 on the CES-D) they could move on to the next step. A score below the cut-off point resulted in a (longer) period of watchful waiting until an elevated score indicated the need for 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.

BOX 1. Stepped care treatment protocol for visually impaired older adults

Step 1 watchful waiting (three months)

The first step was a period of watchful waiting, involving an active decision not to treat the condition but, instead, to intermittently reassess its status. The executive researcher contacted the patient by telephone at baseline (+/- 15 minutes) and after three months of watchful waiting (+/- 15 minutes). Patients could contact the executive researcher by telephone during this period if necessary.

Step 2 guided self-help (three months)

In the second step guided self-help, based on a written, digital, audio and Braille version of a cognitive behavioural therapy (CBT)-based self-help course (with specific vision-related examples and exercises) was offered. The course was divided into seven chapters, aimed at:

1. increasing awareness of depression and anxiety in relation to having a chronic visual impairment, and setting a personal goal.
2. increasing awareness of fatigue and stress in relation to depression and anxiety in people with visual impairment, and offering relaxation exercises.
3. increasing awareness of pleasurable activities that can still be carried out despite being visual impaired, and encouraging to take action.
4. identifying and replacing self-defeating thoughts with healthier thoughts by means of exercises based on rational emotive behaviour therapy (REBT).
5. identifying negative thought patterns (e.g. black-and-white thinking, catastrophic thinking) and replace unhelpful thoughts with helpful thoughts.
6. identifying personal communication styles (passive, assertive or aggressive), and learn to use an assertive communication style.
7. continuing to use learned skills by reflecting on everything that has been learned and setting goals for the future.

Guidance was provided by trained and supervised occupational therapists (*n*=17) from the outpatient low vision rehabilitation organisations. Two face-to-face contacts took place at the beginning of the intervention (+/- 60 minutes each) and one to three telephone calls (+/- 15 minutes each). In the meantime patients followed the intervention at home.

Step 3 problem solving treatment (PST) (three months)

In the third step PST was offered by trained and supervised social workers (*n*=7) and psychologists (*n*=5) of the low vision rehabilitation centres. A maximum of seven face-to-face contacts (+/- 60 minutes each) took place. During each of these contacts the seven steps of PST were completed: 1) clarify the problem, 2) establish realistic goals, 3) generate multiple alternative solutions by brainstorming, 4) explore pros and cons of the alternative solutions, 5) select the best solution, 6) conduct a plan to carry out the best solution, and 7) evaluate the process.

Step 4 referral to the general practitioner (GP)

When elevated symptoms of depression and anxiety still persisted after PST, the executive researcher contacted the patient by telephone to refer him/her to the GP (+/- 15 minutes). The executive researcher called the GP, who made an appointment with the patient to discuss further treatment and the use of medication (+/- 15 minutes).

Outcome measures

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.[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.[24,25] Although a dysthymic disorder requires a depressed mood for over two 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.[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.[20,21] 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)[29,30] and adaptation to vision loss was measured with the Adaptation to Vision Loss (AVL) scale (adapted from the AVL-12,[31] 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 were investigated 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).[32] 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).[32]

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.[33]

Usual care was measured at 6, 12, 18 and 24 months with the Trimbos/iMTA questionnaire for Costs associated with Psychiatric illness (TicP).[34] 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.[34] 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.[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.[36]

Data analysis

An intention-to-treat analysis was performed using SPSS for Windows version 20 (SPSS IBM, New York, USA). First, differences in patient characteristics in the stepped care and usual care group, and in patients who dropped-out and those who completed the follow-up period, were tested for consistency based on independent sample t-tests and χ^2 tests. Second, the absolute and relative risk of developing a depressive and/or anxiety disorder in the usual care versus the stepped care plus usual care group, and the number needed to treat as the inverse of the risk difference, were determined. Third, a survival analysis based on a Kaplan Meier curve, Log-rank test and (adjusted) Cox proportional hazard regression analysis were used to compare differences between the stepped care and usual care groups in time to the onset of a depressive and/or anxiety disorder. Survival analysis was chosen because time played an important role in the present study, as the programme aimed to delay or prevent the onset of a depressive and/or anxiety disorder. Fourth, to investigate the effect of the intervention on the secondary outcomes, linear mixed models using maximum likelihood estimation were performed. Follow-up measurements of the secondary outcomes were adjusted for their baseline value. The intervention effect was defined as the interaction of treatment allocation (stepped care vs. usual care) by time (follow-up until 24 months).

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).

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

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

PST problem solving treatment; GP general practitioner

TABLE 2. Patient characteristics measured at baseline and 24-month healthcare utilisation of the intervention *(n=131)* and control group *(n=134)*

Patient characteristics measured at baseline		**Intervention group**	**Control group**
Female gender (*n* (%))		91 (70%)	94 (70%)
Age in years, range [50-98] (mean (*SD*))		72.4 (12.5)	74.9 (11.9)
Education in years, range [0-16] (mean (*SD*))		10.4 (3.8)	9.3 (3.4)
Nationality (*n* (%))	Dutch	116 (89%)	117 (87%)
	Belgian	14 (11%)	16 (12%)
	Other	1 (1%)	1 (1%)
Living situation (independent) (*n* (%))		115 (88%)	124 (93%)
Income (*n* (%))	Usually enough money	61 (47%)	62 (46%)
	Just enough money	55 (42.%)	57 (43%)
	Not enough money	10 (8%)	15 (11%)
Cause of vision loss (*n* (%))	Macular degeneration	62 (47%)	60 (45%)
	Glaucoma	26 (20%)	19 (14%)
	Cataract	26 (20%)	19 (14%)
	Diabetic retinopathy	5 (4%)	4 (3%)
	Cerebral haemorrhage	5 (4%)	10 (8%)
	Other	45 (34%)	60 (45%)
Time of onset of visual loss in years (median [25-75% percentiles])		8 [3-19]	8 [3-16]
LogMAR visual acuity (*n* (%))	Normal visual acuity*	9 (7%)	15 (11%)
	Mild vision loss	24 (18%)	23 (17%)
	Low vision / blindness	86 (66%)	86 (64%)
Comorbidity range [0-5] (mean (*SD*))		1.1 (1.2)	1.2 (1.2)
History of major depressive disorder (*n* (%))		30 (23%)	25 (19%)
History of dysthymic disorder (*n* (%))		4 (3%)	1 (1%)
History of panic disorder (*n* (%))		8 (6%)	8 (6%)
Mental health services received in three months before baseline (*n* (%))	Information	14 (11%)	13 (10%)
	Practical support	38 (29%)	34 (25%)
	Skills training	5 (4%)	4 (3%)
	Counselling/therapy	20 (15%)	17 (13%)
	Referral to specialist	5 (4%)	4 (3%)
	Medication	17 (13%)	28 (21%)

TABLE 2. Continued

24-month healthcare utilisation / usual care			
General practitioner (number of contacts) (mean (*SD*))		9.4 (10.7)	9.8 (11.3)
Company physician (number of contacts) (mean (*SD*))		0.2 (1.2)	0.2 (1.1)
Medical specialist (number of contacts) (mean (*SD*))		10.4 (16.6)	8.4 (11.8)
Occupational- or physiotherapist (number of contacts) (mean (*SD*))		22.1 (45.1)	26.1 (42.3)
Social worker (number of contacts) (mean (*SD*))		3.4 (8.8)	2.9 (8.2)
Psychologist or psychiatrist (number of contacts) (mean (*SD*))		1.5 (5.1)	1.8 (6.9)
Alternative healer (number of contacts) (mean (*SD*))		0.7 (3.8)	1.4 (5.3)
Group-based peer support (number of contacts) (mean (*SD*))		1.6 (12.6)	1.9 (13.5)
Homecare (hours) (mean (*SD*))		158.8 (287.2)	154.6 (298.2)
Hospitalisation (days) (mean (*SD*))		3.6 (11.4)	5.5 (17.3)
Medication (yes/no) (*n* (%))	Mental health	35 (27%)	46 (34%)
	Other	103 (79%)	107 (80%)

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

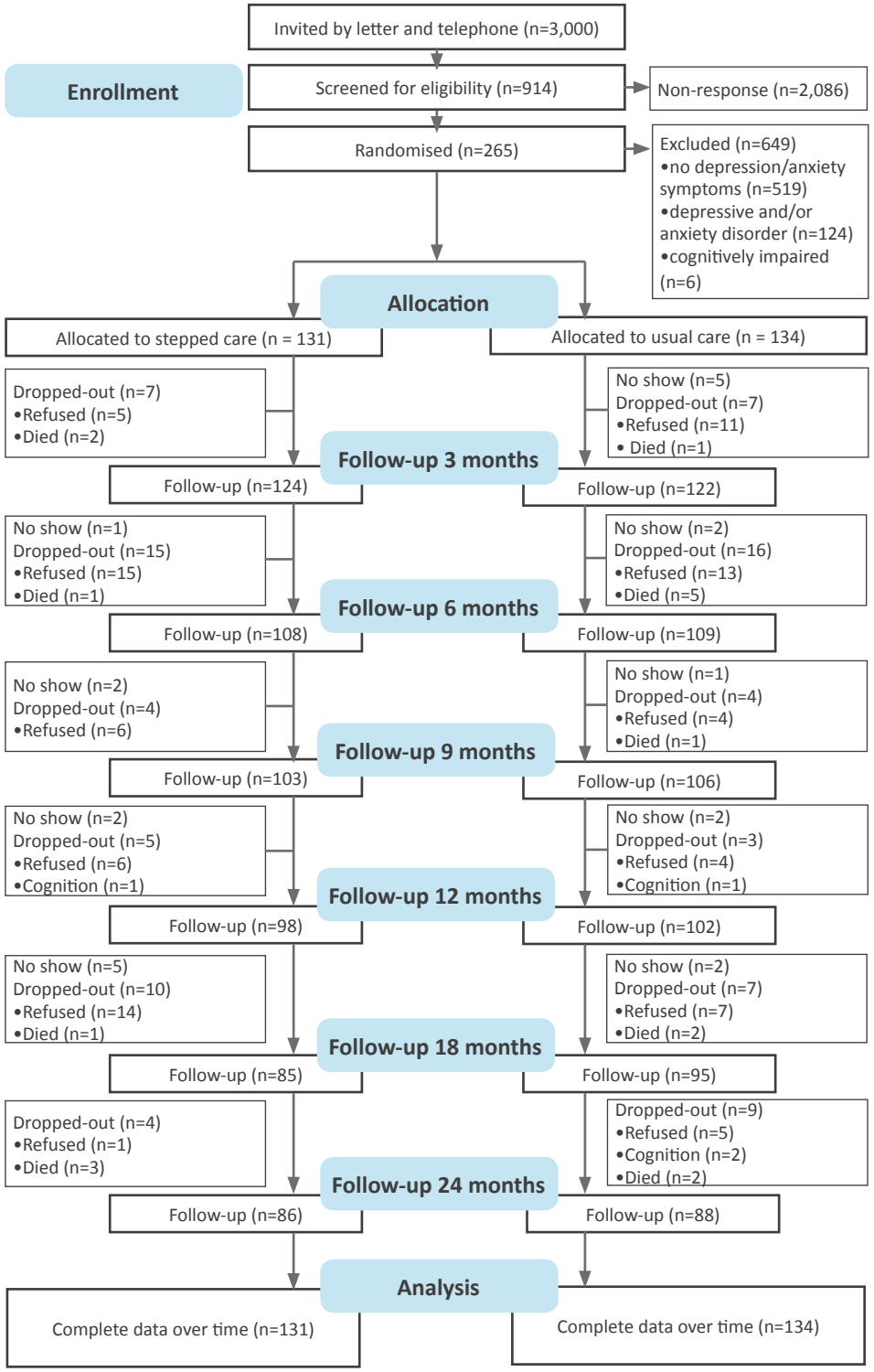

FIGURE 1. Flow diagram of study participants

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 22). 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 (χ^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, χ^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.

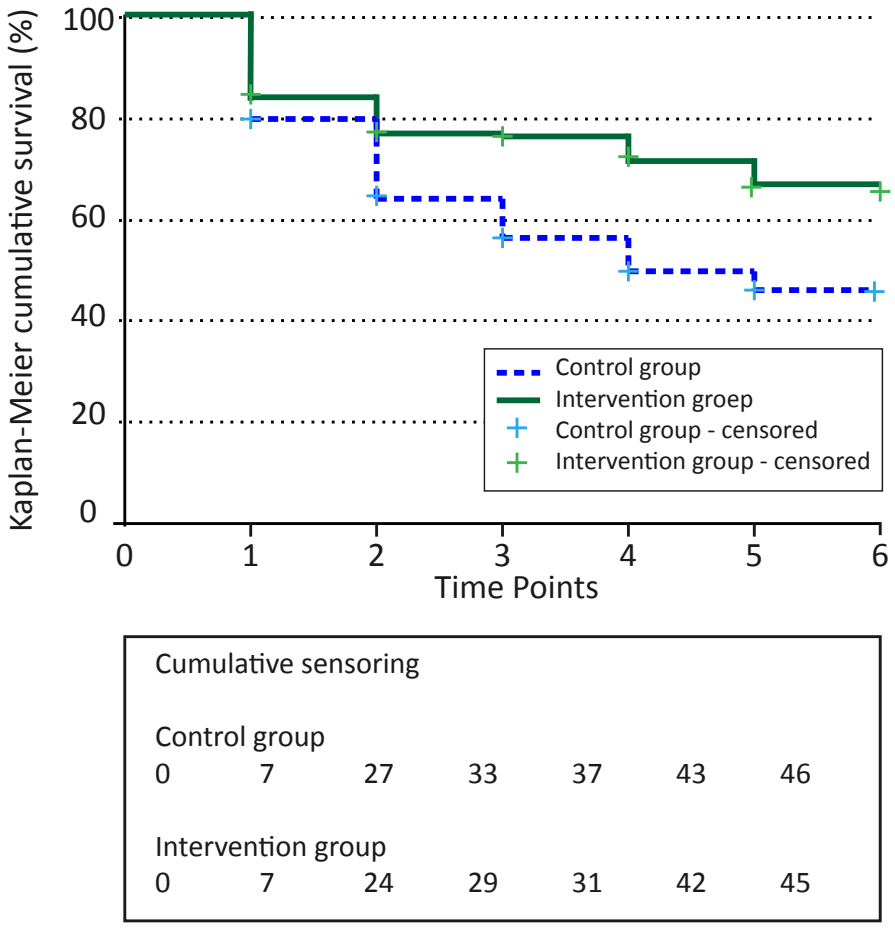

FIGURE 2. Kaplan Meier survival curve comparing the mean survival duration (not developing a major depressive and/or anxiety disorder) of the intervention *(n=131)* and control group *(n=134)* with cumulative censoring per measurement

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

Outcomes (mean (SD))	baseline	3 months	6 months	9 months	12 months	18 months	24 months
Intervention group (n=131)							
Symptoms of depression (CES-D)	21.2 (6.4)	17.5 (9.3)	16.4 (9.5)	15.2 (9.7)	15.1 (9.4)	15.2 (9.4)	15.7 (10.9)
Symptoms of anxiety (HADS-A)	7.1 (4.1)	5.8 (4.1)	5.4 (4.0)	5.0 (4.0)	5.1 (4.4)	5.9 (3.8)	5.6 (4.6)
Vision-related QoL (LVQOL-18)	42.6 (13.2)	-	-	-	41.2 (12.6)	-	42.1 (14.2)
Adaptation to vision loss (AVL-9)	14.1 (5.7)	-	-	-	14.6 (5.9)	-	14.5 (6.4)
Health-related QoL (EQ-5D)	0.7 (0.3)	-	-	-	0.6 (0.3)	-	0.7 (0.3)
Control group (n=134)							
Symptoms of depression (CES-D)	21.1 (6.7)	17.5 (8.4)	19.0 (8.9)	17.4 (8.7)	16.8 (9.8)	17.7 (9.4)	17.7 (9.2)
Symptoms of anxiety (HADS-A)	7.1 (3.8)	5.5 (3.6)	6.3 (3.6)	6.1 (4.3)	6.1 (4.2)	6.5 (3.9)	6.6 (4.3)
Vision-related QoL (LVQOL-18)	43.2 (14.5)	-	-	-	44.3 (13.7)	-	40.8 (15.7)
Adaptation to vision loss (AVL-9)	13.6 (5.7)	-	-	-	14.5 (5.5)	-	14.7 (5.7)
Health-related QoL (EQ-5D)	0.7 (0.2)	-	-	-	0.6 (0.3)	-	0.7 (0.3)

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 EuroqoI-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 8 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)

Treatment components (*n* (%))	**Guided self-help**		**Problem solving treatment**	
	Yes	No	Yes	No
Information and participation:				
I received sufficient information about the method/step	52 (71%)	6 (8%)	20 (69%)	4 (14%)
I received sufficient information about the expected result	43 (59%)	22 (30%)	15 (52%)	8 (28%)
I helped determine treatment possibilities	55 (75%)	10 (14%)	17 (59%)	6 (21%)
Professional:				
The professional had sufficient expertise	48 (66%)	6 (8%)	24 (83%)	0 (0%)
I sufficiently trusted the professional	53 (73%)	5 (7%)	23 (79%)	1 (3%)
The professional showed respect	51 (70%)	6 (8%)	21 (72%)	2 (7%)
Result of the treatment:				
This was the right approach for my problems	48 (66%)	17 (23%)	15 (52%)	8 (28%)
The treatment increased my feelings of control	45 (62%)	20 (27%)	17 (59%)	6 (21%)
My situation sufficiently improved based on this treatment	39 (53%)	21 (29%)	17 (59%)	6 (21%)
I am able to do more things that are important to me	35 (48%)	16 (22%)	21 (72%)	2 (7%)
I can cope better with situations that I previously had difficulty with	42 (58%)	18 (25%)	15 (52%)	8 (28%)
Satisfaction score, range [4-10] (mean (*SD*))	7.54 (1.20)		7.05 (1.00)	

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).[27,28] 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,[10,14] 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,[5] 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 easy 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 have difficulty addressing treatment demand.[1]

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