



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

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ABSTRACT

STUDY QUESTION

Is stepped care compared with usual care effective in preventing the onset of major depressive, dysthymic, and anxiety disorders in older people with visual impairment (caused mainly by age related eye disease) and subthreshold depression and/or anxiety?

METHODS

265 people aged ≥ 50 were randomly assigned to a stepped care programme plus usual care (n=131) or usual care only (n=134). Supervised occupational therapists, social workers, and psychologists from low vision rehabilitation organisations delivered the stepped care programme, which comprised watchful waiting, guided self help based on cognitive behavioural therapy, problem solving treatment, and referral to a general practitioner. 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 generalised anxiety disorder). 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 up to 24 months' follow-up.

STUDY ANSWER AND LIMITATIONS

62 participants (46%) in the usual care group and 38 participants (29%) from the stepped care group developed a disorder. The intervention was associated with a significantly reduced incidence (relative risk 0.63, 95% confidence interval 0.45 to 0.87; $P=0.01$), even if time to the event was taken into account (adjusted hazard ratio 0.57, 0.35 to 0.93; $P=0.02$). The number needed to treat was 5.8 (3.5 to 17.3). The dropout rate was fairly high (34.3%), but rates were not significantly different for the two groups, indicating that the intervention was as acceptable as usual care.

Participants who volunteered and were selected for this study might not be representative of visually impaired older adults in general (responders were significantly younger than non-responders), thereby reducing the generalisability of the outcomes.

WHAT THIS STUDY ADDS

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 screening, monitoring, treatment, and referral of visually impaired older adults with depression and anxiety.

FUNDING, COMPETING INTERESTS, DATA SHARING

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STUDY REGISTRATION

www.trialregister.nl NTR3296.

Introduction

Impaired vision is an important cause of age related disability; 285 million people globally are visually impaired, of whom 65% are aged ≥ 50 .¹ Depression and anxiety are common health problems in visually impaired older adults, whose loss of vision is caused mainly by age related disease such as age related macular degeneration and glaucoma. About a 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 Diagnostic and Statistical Manual of Mental Disorders, fourth edition (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} Care providers, however, underestimate the negative effects of loss of vision 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 that effective psychological interventions—such as self management programmes and problem solving treatment—can reduce depression in visually impaired older adults.^{10,14} These reviews suggest that

WHAT IS ALREADY KNOWN ON THIS TOPIC

Previous studies have shown short term effective results in diminishing depression in visually impaired older adults by offering psychological interventions, such as problem solving treatment and self management programmes

Evidence is scarce, especially concerning treatment of anxiety, and long term effective results are lacking

WHAT THIS STUDY ADDS

Stepped care, in which treatment components were combined and offered only when necessary over a period of one year, was effective in reducing both depression and anxiety in visually impaired older adults, even after a follow-up of two years.

Investigating stepped care in this population was novel and could lead to standard trajectories to deal with depression and anxiety in visually impaired older adults

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 been studied only up to six months,^{10 14} while longer term efforts to monitor and prevent depression and anxiety might 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 specialty of low vision found that stepped care service delivery models, designed to delay or prevent the onset of depression and anxiety in people who show early symptoms, can be effective.¹⁵ Stepped care aims to meet the need for long term management of the disease and maximise the effectiveness and efficiency of resource allocation. Subsequent treatment components are offered by order of intensity—that is, patients start with low intensity interventions and move on to higher intensity interventions only 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 approach depression in older adults.^{16 17} Stepped care, however, has not been investigated in older adults with chronic visually impairment, 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, we investigated the effectiveness of a population specific stepped care programme to prevent the onset of major depressive, dysthymic, and anxiety disorders. In addition, we determined the effects on reducing symptoms of depression and anxiety and improved adaptation to vision loss and quality of life. We hypothesised that stepped care, incorporated in low vision rehabilitation care, would be more effective than usual care alone.

Methods

Study design

This study was a single masked international multicentre randomised controlled trial, exactly as described in the original protocol.¹⁸ Participants were individually randomised in the ratio 1:1 to one of two parallel groups—that is, to usual care or stepped care plus usual care.

Participants

Between July 2012 and April 2013, 3000 patients aged ≥ 50 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 organisations follow the World Health Organization 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 $\leq 30^\circ$ around the central point of fixation and/or an evident request for help for which options in regular ophthalmic practice are not adequate, such as contrast sensitivity or glare. Additional inclusion criteria were having subthreshold depression and/or anxiety—that is, 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}; 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}; being able to speak the Dutch language adequately; and not being severely cognitively impaired (measured with a six item screen, 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

Our prespecified power calculation was based on the study of van ‘t Veer and colleagues,²⁷ who found the proportion of people developing a disorder to be 0.4 in the control group and 0.2 in the intervention group, with a relative risk of 0.5, leading to an effect size of $2 \times \arcsine(\sqrt{0.2}) - 2 \times \arcsine(\sqrt{0.4}) = 0.44$. In addition, we used $\alpha \leq 0.05$ (two sided), power 0.85, and dropout rate 20%, which showed that we needed a minimum of 230 patients (115 in each arm).¹⁸ As dropout rates observed at the start of the trial were higher than expected, we recruited more patients (n=265). Patients were assigned to usual care or the stepped care programme in addition to usual care. A computerised random number generator produced 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. An independent researcher carried out the randomisation after the baseline measurement. 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 were 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 prespecified 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. Because of the nature of the intervention, the participants and therapists could not be masked.

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 (for about 15 minutes) and after three months of watchful waiting (for about 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 self help course based on cognitive behavioural therapy (with specific vision related examples and exercises), was offered. The course was divided into seven chapters, aimed at:
 - Increasing awareness of *depression and anxiety* in relation to having a chronic visual impairment, and setting a personal goal
 - Increasing awareness of *fatigue and stress* in relation to depression and anxiety in people with a visual impairment, and offering relaxation exercises
 - Increasing awareness of *pleasurable activities* that can still be carried out despite the visual impairment, and encouragement to take action
 - Identifying and replacing *self defeating thoughts* with healthier thoughts by means of exercises based on rational emotive behaviour therapy
 - Identifying *negative thought patterns* (for example, black and white thinking, catastrophic thinking) and replace unhelpful thoughts with helpful thoughts
 - Identifying personal *communication styles* (passive, assertive, or aggressive), and learning to use an assertive communication style
 - Continuing to use learned skills by *reflecting* on everything that has been learnt 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 (about 60 minutes each contact) and one to three telephone calls (for about 15 minutes each). In the meantime patients followed the intervention at home

Step 3 Problem solving treatment (three months)

- In the third step trained and supervised social workers (n=7) and psychologists (n=5) from the low vision rehabilitation centres offered problem solving treatment
- A maximum of seven face to face contacts (about 60 minutes each) took place
- During each of these contacts the seven steps of problem solving treatment were completed:
 - Clarify the problem
 - Establish realistic goals
 - Generate multiple alternative solutions by brainstorming
 - Explore pros and cons of the alternative solutions
 - Select the best solution
 - Conduct a plan to carry out the best solution
 - Evaluate the process

Step 4 Referral to a GP

- When increased symptoms of depression and anxiety still persisted after problem solving treatment, the executive researcher contacted the patient by telephone to refer him or her to their GP (about 15 minutes)
- The executive researcher called the GP, who made an appointment with the patient to discuss further treatment and the use of drug treatment (about 15 minutes)

Interventions

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 groups 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 (such as bereavement, fatigue, psychosocial adjustment) that could 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 (for example, 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: watchful waiting, guided self help based on cognitive behavioural therapy, problem solving treatment, and referral to the general practitioner (GP) (box). All treatments were offered individually. Only when patients still had increased symptoms of depression and/or anxiety (score of ≥ 8 on the HADS-A and/or ≥ 16 on the CES-D) could they move on to the next step. A score below the cut-off point resulted in a (longer) period of watchful waiting until an increased score indicated the need for the next 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.

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 general anxiety disorder) according to the DSM-IV, for which the Dutch MINI Plus (5.0.0), developed

in clinician rated format (MINI-CR), was used at baseline and at 3, 6, 9, 12, 18, and 24 months in both groups. 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 κ coefficients for all diagnoses, except for generalised anxiety disorder for which the κ 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 (for example, they had experienced a depressed mood only for the past 1.5 years) could be diagnosed with this disorder by the next time point. History of major depressive, dysthymic, and panic disorder at baseline was 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 symptoms of depression and anxiety in older adults.^{22 23} The HADS-A, also used to measure symptoms of anxiety, has seven items, with a total score ranging from 0-21 and a cut-off score for subthreshold anxiety of ≥ 8 . Its reliability 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 experienced 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 nine questions on a 4 point Likert scale, measuring intrapersonal and interpersonal acceptance of vision loss) at baseline and after 12 and 24 months. Psychometric properties of these questionnaires were investigated with item response theory models. We found no evidence of multidimensionality, local dependence, or differential item functioning, and all scales showed good fit to the model (that is, 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 and 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 We used utility scores based on the Dutch tariff, where 1 denotes full health and 0 means a health state comparable with death (range -0.58 to 1, where negative utilities are valued as worse than death).³²

For the process evaluation, firstly we measured compliance with treatment in step two and three of the programme based on the number of patients who rejected the intervention and the number and duration of appointments. Secondly, we reviewed therapist adherence to the

problem solving treatment protocol based on audiotapes of a random selection of sessions (n=13). Thirdly, we determined adoption of the interventions based on therapists' experiences, measured with two questions ("Are you satisfied with the results of the intervention?" and "Do you think the intervention suited the needs of the patient?") and patients' evaluation of the services, measured with the Dutch mental healthcare thermometer of satisfaction, a widely used 20 item questionnaire.³³

We used the Trimbos/iMTA questionnaire for costs associated with psychiatric illness (TicP)³⁴ to measure usual care at 6, 12, 18, and 24 months. This questionnaire measured self reported use of healthcare 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, admission to hospital, and use of drugs in the past six months.³⁴ At baseline we used the perceived need for care questionnaire (PNCQ) to determine mental health services received in three months before the start of the study. This measured received information about mental illness and treatment possibilities, practical support, skills training, counselling/therapy, and drugs.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 event or stroke, cardiac disease, cancer, and other chronic conditions. Compared with GP information, the accuracy of the self reports of these diseases was shown to be adequate and independent of cognitive impairment.³⁶

Data analysis

We used SPSS for Windows version 20 (SPSS IBM, New York, USA) to perform an intention to treat analysis. Firstly, we tested differences in patients' characteristics in the stepped care and usual care group, and in patients who dropped out and those who completed the follow-up period, for consistency based on independent sample *t* tests and χ^2 tests. Secondly, we determined 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. Thirdly, we carried out a survival analysis based on a Kaplan-Meier curve, log rank test, and (adjusted) Cox proportional hazard regression analysis to compare differences between the stepped care and usual care groups in time to the onset of a depressive and/or anxiety disorder. We chose survival analysis 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. Fourthly, to investigate the effect of the intervention on the secondary outcomes, we performed linear mixed models using maximum likelihood estimation. 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 v usual care) by time (follow-up until 24 months).

Results

Participants

Non-responders (n=2086) were significantly older than responders (n=914, mean difference 4.6 years, $P<0.001$); no significant difference in sex was found. Baseline interviews resulted in the exclusion of 519 responders who had no symptoms of depression/anxiety, 124 who had a depressive/anxiety disorder, and six who were cognitively impaired. The 265 remaining 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 (fig 1). Those who dropped out of the study were significantly older and more 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 death (16% of stepped care and 24% of the usual care group), physically or mentally not able to continue (18% and 22%, respectively), and too great a burden to continue (18% and 17%, respectively).

In the stepped care group, all 131 participants received a period of watchful waiting, 73 (56%) received guided self help, 29 (22%) received problem solving treatment, and seven (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 had developed a full blown depression and/or anxiety disorder and were immediately referred to their GP. There was no significant difference between the stepped care and usual care group in baseline characteristics of patients (table 2) and use of healthcare (table 3), except for level of education ($P<0.05$).

Effectiveness

During the 24 month follow-up, 38 (29%) of the 131 participants in the stepped care group and 62 of the 134 participants (46%) in the usual care group developed a major depressive, dysthymic, and/or anxiety disorder. The absolute difference was 17% (95% confidence interval 13 to 22). The stepped care programme was associated with a significantly reduced incidence of depressive and anxiety disorders, with a relative risk of 0.63 (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 (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 with 18 of the 62 patients in the control group (29%). This difference was 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 significantly 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 (fig 2, $\chi^2=8.2$, $P=0.004$). Cox regression

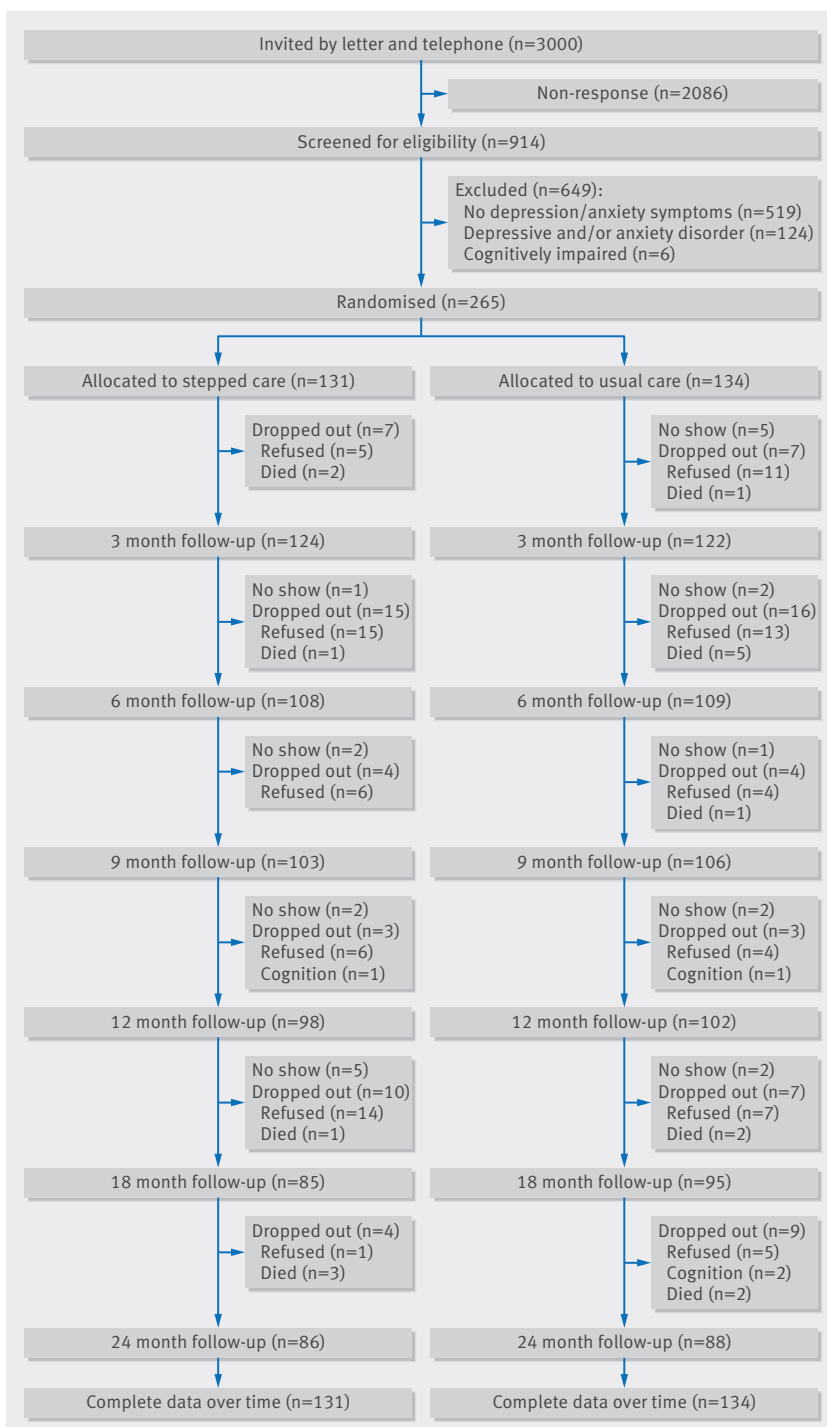


Fig 1 | Flow of participants in study of stepped care for depression and anxiety in visually impaired older adults

Table 1 | Uptake of different steps of stepped care programme for depression and anxiety in visually impaired older adults in intervention group (n=131) over 12 months. Figures are numbers (percentage) of participants

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)
Watchful waiting	131 (100)	—	—	—	131 (100)
Guided self help	—	58 (47)	14 (13)	1 (1)	73 (56)
Problem solving treatment	—	—	18 (17)	11 (11)	29 (22)
Referral to general practitioner	—	—	—	7 (7)	7 (5)

Table 2 | Patients' characteristics measured at baseline in intervention group (n=131; stepped care programme for depression and anxiety in visually impaired older adults) and control group (n=134, usual care). Figures are numbers (percentage) of participants unless stated otherwise

	Intervention group (n=131)	Control group (n=134)
Women	91 (70)	94 (70)
Mean (SD) age (years) (range 50-98)	72.4 (12.5)	74.9 (11.9)
Mean (SD) years of education (range 0-16)	10.4 (3.8)	9.3 (3.4)
Nationality:		
Dutch	116 (89)	117 (87)
Belgian	14 (11)	16 (12)
Other	1 (1)	1 (1)
Living independently	115 (88)	124 (93)
Income:		
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:		
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)
Mean (SD) years since onset (range 0-79)	16.0 (19.6)	14.4 (18.2)
LogMAR visual acuity:		
Normal visual acuity*	9 (7)	15 (11)
Mild vision loss	24 (18)	23 (17)
Low vision/blindness	86 (66)	86 (64)
Mean (SD) No of comorbidities (range 0-5)	1.1 (1.2)	1.2 (1.2)
History of major depressive disorder	30 (23)	25 (19)
History of dysthymic disorder	4 (3)	1 (1)
History of panic disorder	8 (6)	8 (6)
Mental health services received in three months before baseline:		
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)

*Participants with visual field of $\leq 30^\circ$ and/or evident help request for which options in regular ophthalmic practice are not adequate, such as contrast sensitivity or glare.

analysis showed a crude hazard ratio of 0.59 (95% confidence interval 0.38 to 0.91; $P=0.02$) and an adjusted hazard ratio of 0.57 (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.

We observed significant intervention effects after 24 months for the CES-D (group difference -0.57 , 95% confidence interval -1.04 to -0.10 ; $P=0.02$), the HADS-A (-0.21 , -0.41 to -0.01 ; $P=0.04$), and the LVQOL-18 (3.81,

0.65 to 6.96; $P=0.02$) in favour of stepped care. There were no significant intervention effects, however, for the AVL-9 (0.19, -1.13 to 1.51; $P=0.8$) and the EQ-5D (0.02, -0.05 to 0.09; $P=0.6$). Table 4 shows the observed mean summary scores for the secondary outcomes per measurement for the stepped care and usual care group.

Process evaluation

Out of 73 patients who were eligible for guided self help, six refused and 12 only partly received it. Out of 29 patients who were eligible for problem solving treatment, five refused and four only partly received it. The main reasons were that participants did not believe this kind of help was necessary (37%) and it was too great a burden to follow the intervention (28%). In four cases, patients received more help with the self help course than planned in the protocol—for instance, 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) sessions of problem solving treatment took place. In two patients, the therapist offered more support than the planned maximum of seven sessions (one patient received eight and another patient received 11 sessions). Audiotapes showed fidelity to the problem solving treatment protocol. In two cases, however, 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 often satisfied with the result (68%) and believed that problem solving treatment suited the needs of patients (63%). Table 5 presents information on patient evaluation of services. Lower satisfaction scores were not associated with the development of depressive and/or anxiety disorders after 24 months of follow-up (Mann-Whitney U test, guided self help, $P=0.6$; problem solving treatment, $P=0.7$).

Discussion

Compared with usual care, in this study stepped care had a significant preventive effect on the development of depressive and anxiety disorders in older adults with visual impairment (caused mainly by age related eye disease) over a two year period (adjusted hazard ratio 0.57) and significantly reduced symptoms of depression and anxiety and improved vision related quality of life. These outcomes resemble those from another study that showed a stepped care programme for older adults (age ≥ 75) in the general population was effective in preventing depressive and anxiety disorders.^{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. Prevention of these disorders will have a positive impact on many different aspects of patients' lives and could lead to a reduction of societal costs (such as healthcare costs and productivity).

We combined treatment components and monitored patients over a two year period by offering support only

Table 3 | Healthcare use over 24 months in intervention group (n=131; stepped care programme for depression and anxiety in visually impaired older adults) and control group (n=134; usual care). Figures are means (SD) unless stated otherwise

	Intervention group (n=131)	Control group (n=134)
No of contacts with:		
General practitioner	9.4 (10.7)	9.8 (11.3)
Company physician	0.2 (1.2)	0.2 (1.1)
Medical specialist	10.4 (16.6)	8.4 (11.8)
Occupational or physiotherapist	22.1 (45.1)	26.1 (42.3)
Social worker	3.4 (8.8)	2.9 (8.2)
Psychologist or psychiatrist	1.5 (5.1)	1.8 (6.9)
Alternative healer	0.7 (3.8)	1.4 (5.3)
Group based peer support	1.6 (12.6)	1.9 (13.5)
Homecare (hours)	158.8 (287.2)	154.6 (298.2)
Admission to hospital (days)	3.6 (11.4)	5.5 (17.3)
No (%) receiving medication (yes/no):		
Mental health	35 (27)	46 (34)
Other	103 (79)	107 (80)

when needed, based on increased 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 needed all four steps of the programme and all patients were included in the analyses.

Many participants (38% of the total study population) still 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 control group. This indicates that the stepped care programme was less effective for people with a history of a disorder and that the programme mainly prevented first episodes

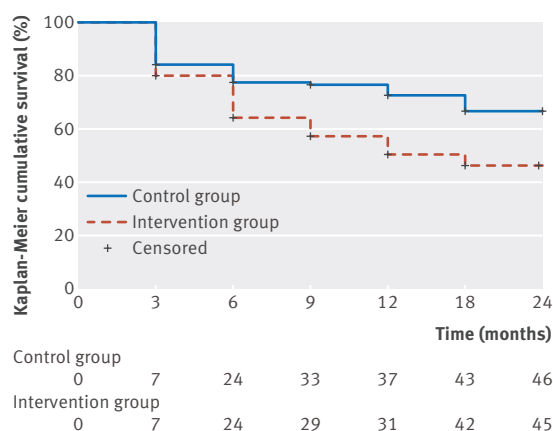


Fig 2 | Kaplan-Meier survival curve for mean survival duration (not developing major depressive and/or anxiety disorder) in intervention group (n=131; stepped care programme for depression and anxiety in visually impaired older adults) and control group (n=134; usual care) with cumulative censoring per measurement

of these disorders. The programme might therefore be less suitable 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 studies of psychological interventions for people with impaired vision. Dropout rates were high but acceptable, and treatment fidelity was largely maintained. The pragmatic design of the study greatly enhances the generalisability of the results, which could lead to widespread implementation within low vision rehabilitation care. In contrast with previous trials in low vision, we examined both depression and anxiety, which is relevant considering the high comorbidity of these disorders,⁵ and investigated a model for long term management of disease, during which support was offered only when needed based on increased 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 might not have been identified. This highlights the need for such procedures within models of delivery of low vision care.

This study also has some limitations. Firstly, 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. Secondly, selection bias might have occurred because patients who volunteered and were selected for this study might have differed from other eligible individuals, thereby reducing the generalisability of the outcomes. Responders were significantly younger than non-responders, and participants had fewer cognitive and physical problems and might, for instance, have had better access to healthcare and been more motivated based on hope of personal gain. Thirdly, both low vision staff and patients were unmasked, which could have led to some information bias—for instance, participants in the stepped care group might have had more attention on treatment outcomes, leading to an overestimation of the results. The low κ coefficient for diagnosis of generalised anxiety disorder with the MINI could have led to overidentification or underidentification of this disorder. In addition, not to overcomplicate interpretation of the secondary outcomes, effect estimates analysed with item response theory models that are increasingly used in ophthalmology, optometry, and low vision were not reported here. With these models, the effect estimates were similarly significant, except for vision related quality of life (data not shown). Finally, the dropout 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

Table 4 | Secondary outcomes at baseline, 3, 6, 9, 12, and 24 months for intervention group (n=131; stepped care programme for depression and anxiety in visually impaired older adults) and control group (n=134; usual care). Figures are means (SD)

Outcomes	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)

CES-D=Centre for Epidemiologic Studies Depression; HADS-A=Hospital Anxiety and Depression Scale-Anxiety; QoL=quality of life; LVQO=Low Vision Quality of Life Questionnaire; AVL=Adaptation to Vision Loss; EQ-5D=Euroqol-5 Dimensions.

Table 5 | Patient evaluation of services in stepped care for depression and anxiety in visually impaired older adults. Figures are numbers (percentage) of participants unless stated otherwise

Treatment components	Guided self help (n=73)		Problem solving treatment (n=29)	
	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)

*Mean (SD) satisfaction score (range 4-10) was 7.5 (1.2) for guided self help and 7.0 (1.0) for problem solving treatment.

psychological intervention study performed in the specialty of low vision (seven measurements in two years). Dropout rates were not significantly different for the stepped care and control groups, indicating that the intervention was equally acceptable as usual care. We do need to realise, however, 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

Our findings 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 sub-threshold 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 guided self help course based on cognitive behavioural therapy were sufficient to reduce depressive and anxiety symptoms. These low intensity and low cost interventions can fairly easily be implemented in low vision rehabilitation care because of their accessibility (that is, people with vision impairment do not have to travel), focus on empowerment, and low intensity of necessary resources (that is, professional support).

In addition, screening and monitoring procedures should be incorporated in low vision rehabilitation care as 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 as eye diseases are often degenerative, which can 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 benefited from the stepped care programme.

In a future study we will examine the costs and cost effectiveness of the stepped care programme compared with usual care. This is highly relevant in a specialty in which numbers of patients are vastly increasing (caused by demographic ageing in developed countries), and healthcare systems already have difficulty dealing with demand for treatment.¹

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Contributors: The executive researcher (HPAvdA), project leader (GHMBvR), clinical psychology advisor (HCC), and principal investigator (RMAvN) conceived the study and its design. HPAvdA, THM (project advisor), and RMAvN performed literature searches. HPAvdA, GHMBvR, and RMAvN developed the stepped care programme based on a qualitative study in close collaboration with

patient representatives and professionals from low vision rehabilitation centres. Data collection was monitored by HvdA and RvN. A statistical analysis plan was developed by HvdA, FG-G, and JWRT (statisticians). Data analysis and interpretation was performed by HvdA, with support from FG-G, JWRT, and RMAvN. HPAvdA drafted the manuscript, which was revised by the other authors (GHMvR, HCC, THM, FG-G, JWRT, and RMAvN). All authors read and approved the final manuscript. GHMvR is guarantor.

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Ethical approval: The study protocol was approved by the medical ethics committee of the VU University Medical Centre in Amsterdam, Netherlands, and the University Hospital Leuven in Belgium and has been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. All participants provided written informed consent to participate in this study.

Data sharing: Full dataset and statistical code is available from the corresponding author. Consent was not obtained but the presented data are anonymised and risk of identification is low.

Transparency: The corresponding author affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; no important aspects of this study have been omitted; and any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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