Chapter 6:

Stepped care to prevent depression and anxiety in visually impaired older adults – design of a randomised controlled trial

Abstract

Background
Subthreshold depression and anxiety are prevalent in the growing population of visually impaired older adults and increase the risk of full-blown depressive and anxiety disorders. Adequate treatment may prevent the development of depressive and anxiety disorders in this high risk group.

Methods
A stepped care programme was developed based on previously found effective interventions and focus group meetings with professionals and patient representatives from three outpatient low vision rehabilitation organisations in the Netherlands and Belgium. The final programme consisted of four steps: 1) watchful waiting, 2) cognitive behavioural therapy-based guided self-help, 3) problem solving treatment, 4) referral to the general practitioner. The cost-effectiveness of this programme will be evaluated in a randomised controlled trial. Patients will be randomly assigned to either the treatment group (receiving stepped care in addition to usual care) or the control group (receiving usual care only). The primary outcome is the incidence of major depressive and anxiety disorders, measured with the Mini International Neuropsychiatric Interview (MINI).

Discussion
Treatment of depression and anxiety has received little attention in the field of low vision. If the intervention proves effective, this study will result in evidence-based treatment options to address depression and anxiety in visually impaired patients. The pragmatic design greatly enhances the generalisability of the results. However, a limitation is the difficulty to investigate the contribution of each individual step of the programme.

Introduction

According to the World Health Organisation, 285 million people worldwide are visually impaired, of whom 65% are 50 years or older.[1] Due to an aging population the prevalence of visual impairment in developed countries will increase in the future.[1] In 2008, 311,000 people in the Netherlands were visually impaired; this number is estimated to increase with 18% to 367,000 people by the year 2020.[2]

Depression and anxiety are common in visually impaired older adults. Recent studies suggest that approximately one-third (range 22-42%) of this population experience mild but clinically significant depressive and/or anxiety symptoms, also known as subthreshold depression and/or anxiety.[3-6] This is at least twice as high as the prevalence in the general population (10-15%).[7] It is important to treat symptoms of depression and anxiety in an early stage, because these are the most important predictors of developing full-blown depressive or anxiety disorders according to DSM-IV criteria, such as major depressive disorder, phobic disorders or generalized anxiety disorder.[8-10] Depression and anxiety can have adverse consequences for health-related quality of life, increase healthcare utilisation, and often accompany disabling diseases and aggravate existing disability.[7,11,-13]

Systematic reviews show that interventions aimed at depression in people with visual impairment can be effective.[14,15] Horowitz et al.[16,17] found that low vision rehabilitation services, such as counselling and use of optical devices, had a small positive effect on the decline of depressive symptoms after two years. Brody et al.[18] found that a self-management programme consisting of cognitive and behavioural elements including health education and enhancement of problem-solving skills, significantly reduced depressive symptoms in people with age-related macular degeneration (AMD) after six months. Girdler et al.[19] also evaluated a self-management programme incorporated in low vision rehabilitation care and reported significantly less depressive symptoms at 12 weeks in participants who received the programme as opposed to participants who received standard visual rehabilitation services. Rovner et al.[20] found that problem solving treatment (PST), a short behavioural treatment in which participants learn a new method to address problems that interfere with everyday functioning, prevents the onset of depressive disorders in elderly people with AMD after two months. However, after six months there was no statistically significant difference in depressive disorders between the intervention- and control group. To prevent the onset of depression on the long term Rovner et al.[20] suggest to either continue treatment after providing PST or focus on preventive treatment for patients that show early signs of depression.

These studies suggest that low vision rehabilitation services, self-management programmes and PST can be effective in addressing depression in visually impaired people. However, evidence is limited and studies were only focused on depression and not on anxiety. Moreover, economic evaluations are completely missing.

This project aims to design and test the cost-effectiveness of a stepped care programme to prevent the onset of major depressive and anxiety disorders in visually impaired older adults (50 years and older) with subthreshold depression and/or anxiety, in three low vision rehabilitation organisations in the Netherlands and Belgium. By reducing symptoms of depression and anxiety, the intervention is expected to positively influence vision- and health-related quality of life and adaptation to vision loss. It is an indicated preventive intervention, aimed at persons who show early signs of depression and/or anxiety but do not meet the diagnostic criteria. The aim is to prevent or delay the onset of major disorders and to reduce the severity and shorten the duration of existing symptoms.

Stepped care comprises different treatment components, such as self-help and PST. The general idea is that if the first, less intensive step does not lead to a reduction of symptoms, then a patient

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moves to a next step which consists of a more intensive and expensive treatment type. This type of intervention is expected to be efficient, because not all patients need the same type or intensity of treatment.[21] Studies in various populations show favourable results for stepped care in reducing depression.[22] Furthermore, both the Multidisciplinary guidelines for mental healthcare in the Netherlands and the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom recommend using a stepped care model to address depression in older adults.[23,24]

Methods

Development of a population-specific stepped care programme

Previous study
Van 't Veer et al. showed that a stepped care programme for older adults in general practice (75 years and older) was effective in preventing depressive and anxiety disorders after 12 months,[25] with effects sustaining after 24 months.[26] This programme consisted of a period of watchful waiting, bibliotherapy (the use of reading materials as guidance), PST and referral to the general practitioner (GP). This programme is used as an example to develop the stepped care programme for people with visual impairment. A recent systematic review showed that cognitive behavioural therapy (CBT) and PST can prevent the development of depression and anxiety in patients with subclinical manifestations of these disorders.[27] Both treatment types help patients to acknowledge their symptoms and encourage them to switch to more active self-management strategies.[27]

Focus group meetings
Healthcare workers and patient representatives of the low vision rehabilitation organisations were involved in developing the protocol by means of several focus group meetings. The initial protocol, based on the study of van 't Veer et al.,[25-26] was discussed in one focus group meeting with 12 low vision healthcare workers (i.e. social workers and psychologists) and two focus group meetings with each 4 patient representatives (one in the Netherlands and one in Belgium). Different aspects of the stepped care programme were discussed: intensity of guidance, type of healthcare workers within rehabilitation organisations who could offer guidance, accessibility of the intervention and ways to stimulate patients to participate. Based on these group meetings the initial protocol was adjusted. After the adjustments, the protocol was sent to the same healthcare workers and patient representatives. After revisions, the final content of the protocol was determined.

Final protocol

Figure 1 shows the final stepped care programme, which consists of four consecutive steps. Each step takes approximately three months. Only if symptoms of depression and/or anxiety persist, patients move on to the next step. Symptoms of depression and anxiety are measured with the Epidemiologic Studies Depression scale (CES-D)[28,29] and the Hospital Anxiety and Depression Scale – Anxiety (HADS-A).[30] Only if patients have a score of 16 or higher on the CES-D and/or a score of 8 or higher on the HADS-A, then they move on to the next step.
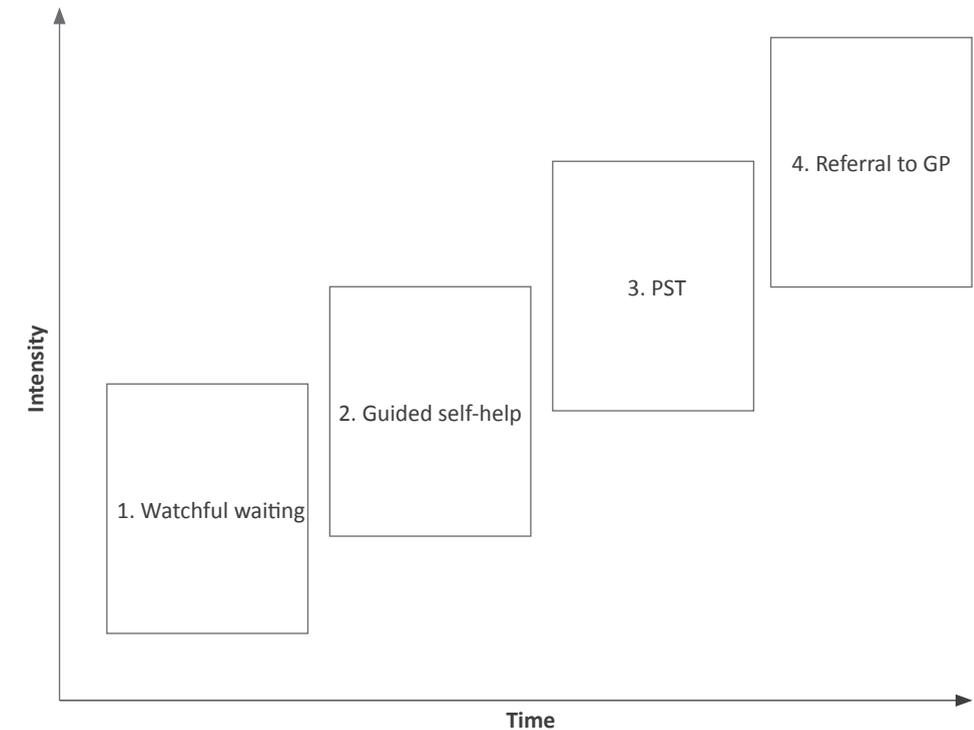

FIGURE 1. Stepped care model

Step 1: Watchful waiting
In the first step, patients are followed to see if symptoms of depression and/or anxiety recover spontaneously. Patients are contacted by the researcher (first author) at the beginning of this step to discuss problems and give an explanation of this first step of the programme. Patients are told that they can contact the researcher during this period if necessary, for example if symptoms of depression and/or anxiety get worse or questions arise. In several studies it was shown that symptoms of depression and anxiety may recover spontaneously during this first period.[31-33]

Step 2: Guided self-help
In the second step, an extended and altered version of the 'Coping with Depression' self-help course is offered, with elements of CBT. This course has been found effective in preventing major depressive and anxiety disorders in community subjects and is used in routine practice in several countries.[34] The altered course is called "Glance at your Dip" ('Blik op je Dip' in Dutch).

Based on the focus group meetings, the self-help course was rewritten and adapted specifically for older adults with visual impairment, e.g. by adding examples of problems people often encounter in daily life due to their visual impairment. The self-help course is offered in a written (large font), a digital, an audio and Braille version. The course helps patients to address depressogenic and anxiogenic thinking, improve social skills and increase pleasant activities and relaxation. The aim is to help patients cope with problems related to one's symptoms of depression and/or anxiety, such as vision loss.

Guidance in following the self-help course is provided by occupational therapists who received a one-day training (by the first and last author). Training consisted of information about depression and anxiety, an explanation of the stepped care programme in total, the self-help course and techniques to motivate patients in addressing their problems.

In this second step of the programme, the trained occupational therapists contact the patients by telephone and introduce the course. If the patient agrees, two face-to-face contacts (at the rehabilitation organisation or at home) take place. Subsequently, the occupational therapist conducts several telephone calls and may schedule another face-to-face contact to encourage patients to continue with the course. The aim of the contacts is 1) to explore the symptoms of depression and anxiety, 2) to reflect on these symptoms by exploring everyday problems, 3) to create awareness of the problems and the possibility to address them, 4) to encourage participants to complete/continue the self-help course. The first two goals help to establish a working relationship between the patient and the occupational therapist. The second two goals help patients recognise their problems and the possibility to address them even in an early stage of the complaints.

Older adults who feel depressed often find it difficult to find the energy and motivation to work on their problems. Therefore, techniques of Motivational Interviewing (express empathy, roll with resistance not fight it, support self-efficacy) are used to stimulate this. Research shows that these techniques can be effective in stimulating patients in seeking and accepting help and making changes in their behaviour.[35]

The researchers (first author; social worker and last author; psychologist), who developed the self-help course, monitor the execution of the intervention by keeping in close contact with the occupational therapists by telephone and e-mail (at least one contact every two weeks) and by organising a peer group meeting to share experiences and learn from each other. Additionally, occupational therapists and patients are asked to evaluate the self-help course on a written evaluation form. They are asked what they think about the intervention, about the guidance that was given and about the results.

Step 3: Problem Solving Treatment (PST)
When patients still have elevated scores on the CES-D or HADS-A after step 2, they receive PST by a trained social worker or psychologist from the low vision rehabilitation organisation. PST is a short evidence-based behavioural treatment which helps patients to regain control of their life, which reduces feelings of depression and anxiety.[36] With PST, the patient learns to identify and address problems that interfere with everyday functioning and lead to feelings of depression and anxiety by means of 7 different steps: 1) clarifying the problem, 2) establishing a realistic goal to address the problem, 3) generating multiple solution alternatives, 4) exploring the pros and cons for each possible solution, 5) choosing the preferred solution, 6) identifying the specific steps needed to carry out the solution, 7) after trying to implement the solution, in the next meeting the process will be evaluated.

Experienced social workers and psychologists from the low vision rehabilitation organisations received a one-day training in two groups by a qualified PST trainer and supervisor (psychologist, PhD) with experience in stepped care. Information about the techniques and different steps of PST was given and was practiced in role-plays. After that, all social workers and psychologists piloted their learned skills on a patient that did not participate in this study.

In this third step of the programme the social worker or psychologist contacts the patient by telephone and introduces PST. If the patient agrees, subsequently a maximum of seven face-to-face contacts (at the rehabilitation organisation or at home) take place in which the stages of PST are explained and applied to problems encountered in daily life. Patients choose their

own problems to work on and are able to use a list (large font) of potential problems (related to physical-, psychological-, practical- and social functioning) to help them think of problems to address. Furthermore, a CD with the different steps of PST is given to patients as a reminder for practising at home in between the meetings.

To secure fidelity with the intervention, a qualified PST trainer and supervisor (psychologist, PhD) guides social workers and psychologists in performing PST, by means of telephone calls and e-mail. In addition, a peer group meeting is organised to share experiences and learn from each other. Two sessions per patient are audio-taped to have a good understanding of the process. The supervisor and researcher (first author) review these tapes. Additionally, social workers, psychologists and patients are asked to evaluate the process. They are asked what they think about the intervention, about the guidance that was given and about the results.

Step 4: Referral to General Practitioner (GP)
When symptoms persist, patients are referred to their GP to discuss further (more intensive) treatment and to discuss the use of medication. GPs are the so called 'gate-keepers' for all (mental) healthcare facilities in the Netherlands. They can refer patients to other care providers or may prescribe medication. If patients are diagnosed with a depressive or anxiety disorder during the study, as measured with the Mini International Neuropsychiatric Interview (MINI),[37] they are directly referred to their GP to discuss further treatment and medication. Not all patients in the intervention group complete all phases of the stepped care intervention, because treatment is only initiated if symptoms of depression and/or anxiety remain elevated. Patients who recover enter a period of 'watchful waiting'. When elevated symptom levels again indicate a need for treatment, the following step of the intervention is initiated.

Design of a randomised controlled trial (RCT)
A two-armed multicentre international RCT will be performed, conducted at two rehabilitation organisations in the Netherlands and one in Belgium, to evaluate the cost- effectiveness of the stepped care programme in comparison with usual care to prevent depressive and anxiety disorders in visually impaired older adults with subthreshold depression and/or anxiety. The study protocol was approved by the Medical Ethics Committee of the VU University Medical Centre in Amsterdam and the University Hospital Leuven. It is conducted according to the principles of the Declaration of Helsinki. Patients are fully informed about the study and give written informed consent. They are allowed to withdraw their consent at any time during the study.

Setting
Low vision rehabilitation organisations in the Netherlands and Belgium operate at the interface between health care and social care. They support people with vision loss by training them to make use of their residual vision and cope with everyday problems aimed at home-, leisure-, school-, work or other activities and participation issues. A programme to address depression and anxiety, in addition to usual visual rehabilitation care, fits well within this setting.

Recruitment
The invitation of patients (approximately *n*=3,000) is done in four waves, with three months in between (September 2012, December 2012, March 2013 and June 2013). This is to avoid the need for all patients having to be treated at the same time. Patients from the low vision rehabilitation organisations who are 50 years or older receive an information letter and an informed consent form. After they give written consent to participate, they are screened for eligibility.

Participants
Visually impaired older adults with subthreshold depression or anxiety, but no actual depressive or anxiety disorder according to the DSM-IV, with sufficient knowledge of the Dutch language, without severely impaired cognitive functioning and capable to give informed consent are eligible

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to participate. Depressive symptoms are measured with the CES-D[28,29] and anxiety symptoms with the HADS-A. Visually impaired older adults who have a score of ≥16 on the CES-D or a score of ≥8 on the HADS-A are eligible to participate. If participants have a depressive or anxiety disorders according to the DSM-IV as measured with the Mini International Neuropsychiatric Interview (MINI Plus 5.0.0. in clinician-rated format) they are excluded from the study.[37] Cognitive functioning is evaluated by means of a six-item screener. This is a modified version of the Mini-mental state examination (MMSE), with a score of 3 or more errors indicating cognitive problems.[37] Patients who have no complaints and patients with a depressive or anxiety disorder after the first screening are not randomised but are followed in this study to see how symptoms develop over time.

Randomisation
Patients are randomly assigned to either the intervention group (stepped care programme in addition to usual care) or the control group (usual care). Randomisation is performed by means of a computer-generated allocation scheme based on blocks of two, stratified by 17 different locations of the three low vision rehabilitation organisations. Usual care consists of the support low vision rehabilitation organisations normally offer to visually impaired older adults and/or care that is received by other providers on the initiative of patients.

Blinding
Blinding of participants and therapists is not possible due to the nature of the intervention. However, the principal investigator and research assistants who perform the interviews are masked until after the primary outcomes of the study are analysed.

Measurements
Seven measurements take place by means of telephone interviews. One at baseline and thereafter at every step of the intervention (at 3, 6, 9 and 12 months) and at follow-up (at 18 and 24 months). Outcome measures are obtained over the phone by blinded research assistants, who are trained (by the first author) to follow a predetermined protocol. The first interview takes approximately 45 minutes; the next interviews take approximately 30 minutes. In Figure 2 an overview of the design is presented.
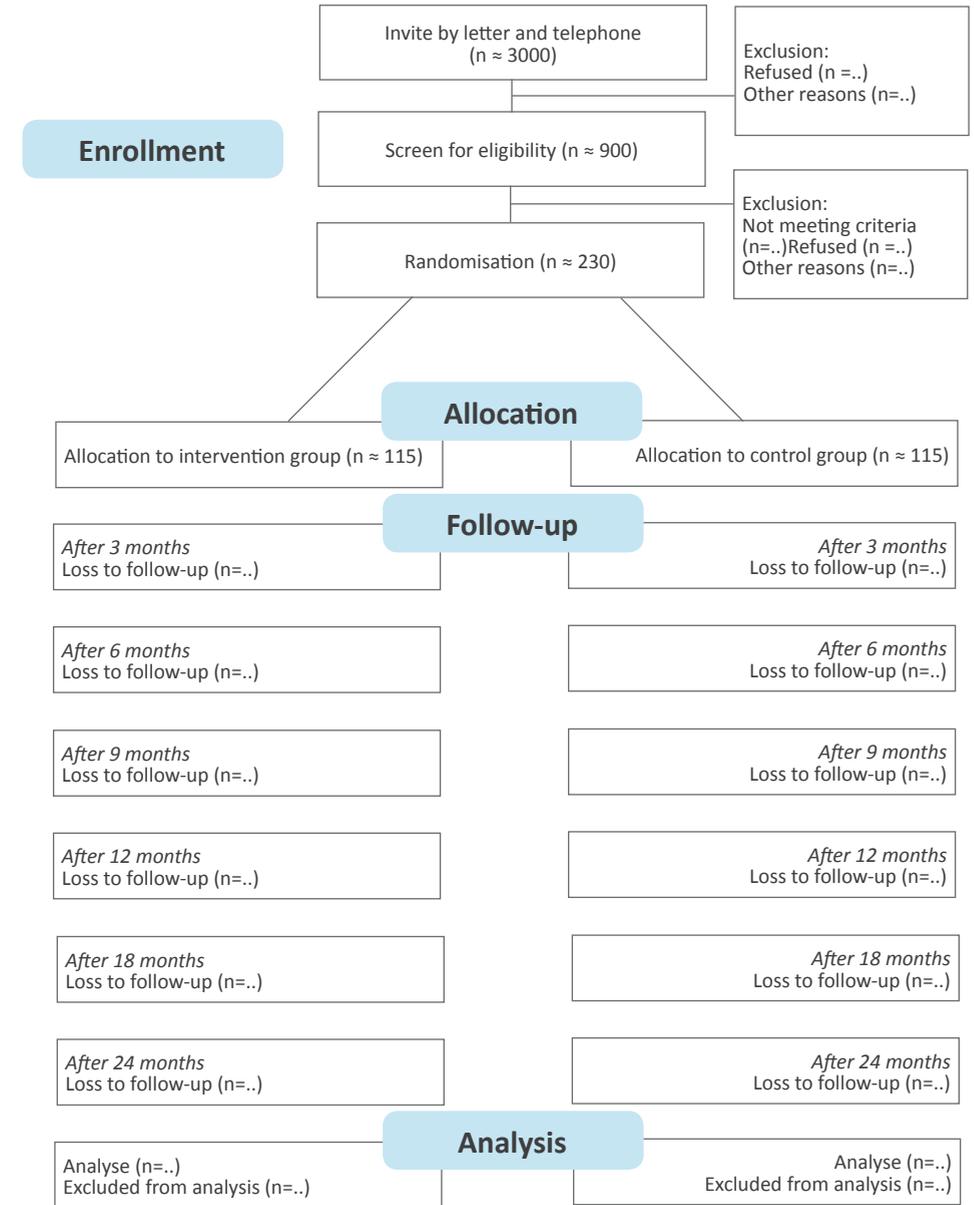

FIGURE 2. Overview of the RCT design

Outcomes

The primary outcome of this study is the incidence of depressive (major depressive disorder and dysthymia) and anxiety disorders (panic disorder (with and without agoraphobia), agoraphobia (without a history of panic disorder), social phobia and generalized anxiety disorder) as measured with the Mini International Neuropsychiatric Interview (MINI Plus 5.0.0. in clinician-rated format), using the electronic version MiniManager 2.0 (de Beurs, Leiden University Medical Centre). Secondary outcome measures are subthreshold depression measured with the CESD[28,29] and subthreshold anxiety measured with the HADS-A.[40] Other secondary outcome measures are vision-related quality of life as measured with the Low Vision Quality Of Life questionnaire (LVQOL)[39,40] and health-related quality of life measured with the EuroQol-5 Dimensions (EQ-5D).[41] In addition, adaptation to vision loss is measured with the Adaptation to age-related Vision Loss (AVL) questionnaire[42] and perceived need for care is measured with the Perceived Need for Care Questionnaire (PNCQ).[43] For the process-evaluation the Dutch Mental Healthcare Thermometer is used to evaluate the different steps of the stepped care programme.[44] For the cost-evaluation the Trimbos/iMTA questionnaire for Costs associated with Psychiatric illness (TicP) is used to measure healthcare utilisation,[45] and the Short Form Health and Labour Questionnaire (SF-HLQ) to measure absenteeism and presenteeism from paid and unpaid work.[46] Standard costs for healthcare utilisation from the Dutch costing guidelines are used.[47] Medication use is valued using prices of the Royal Dutch Society of Pharmacy. Productivity losses will be valued using the human capital and friction cost approach. In Table 1 the different outcome measures are presented per follow-up measurement.

TABLE 1. Outcome measures, instruments and assessments at baseline, after 3, 6, 9, 12, 18 and 24 months

	T0	T1	T2	T3	T4	T5	T6
		3m	6m	9m	12m	18m	24m
Primary Outcome:							
Depression or anxiety disorder (MINI) [48]	x	x	x	x	x	x	x
Secondary Outcomes:							
Subthreshold depression (CES-D) [38, 39]	x	x	x	x	x	x	x
Subthreshold anxiety (HADS-A) [40]	x	x	x	x	x	x	x
Six item screener [49]	x						
Vision-related quality of life (LVQOL) [50, 51]	x			x			x
Health-related quality of life (EQ-5D) [52]	x			x			x
Adaptation to age-related Vision Loss (AVL) [53]	x			x			x
Perceived need for care (PCNQ) [54]	x	x	x	x	x	x	x
Patient satisfaction (MH thermometer) [62]		x	x	x	x		
Healthcare utilisation (Tic-P) [56]	x		x		x		x
Health and labour (SF-HLQ) [57]	x		x		x		x

CES-D Centre for Epidemiologic Studies Depression scale; HADS-A Hospital Anxiety and Depression Scale – Anxiety; LVQOL Low Vision Quality of Life Questionnaire; EQ-5D Euroqol-5 Dimensions; AVL Adaptation to Vision Loss scale; PNCQ Perceived Need for Care Questionnaire; MH Mental Healthcare; Tic-P Trimbos/iMTA questionnaire for Costs associated with Psychiatric illness; SF-HLQ Short Form Health and Labour Questionnaire.

Sample size

The power calculation is based on the study of van 't Veer et al.[25] in which a comparable stepped care programme was tested in older adults. Results from this study showed that over a period of two years approximately 40% of older adults in the control group, who were not depressed at baseline, became depressed during this study, versus 20% of older adults in the intervention group. Therefore, it is expected that the programme will lead to a reduction of depressive and anxiety disorders of 50% (approximately 20% versus 40%). Based on a power of 85%, a significance level of 0.05 (two-sided) and a drop-out rate of 20%, 115 patients are needed in each group. Approximately 3,000 visually impaired patients (aged ≥50 years) of one of the rehabilitation organisations, are invited to participate in the screening for this study. We expect that approximately 30% is willing to cooperate, resulting in 900 patients who can be screened for symptoms of depression and anxiety with the CES-D and HADS-A and on depressive and anxiety disorders with the MINI, by means of a telephone interview. This will result in approximately 230 eligible patients.

Statistical analysis

The analyses are based on the intention-to-treat principle. Statistical analyses are performed using SPSS for Windows version 20 (SPSS IBM, New York, USA). First, descriptive statistics of baseline characteristics are compared to check whether randomisation is successful in generating two similar groups. Survival analyses and mixed modelling is then used to compare the treatment and control group. All available data in all measurement cycles are used to estimate the longitudinal trial outcomes at 3, 6, 9, 12, 18 and 24 months after baseline.

For the economic evaluation multiple imputation is used to impute missing data. Bias-corrected and accelerated bootstrapping with 5000 replications is used to estimate 95% confidence intervals around the mean difference in total costs between the treatment and control group. Incremental cost-effectiveness ratios (ICERs) are calculated. Bootstrapping is used to estimate the uncertainty surrounding the ICERs. Cost-effectiveness acceptability curves and net monetary benefits are also estimated.

Discussion

Depression and anxiety are common in visually impaired older adults and this elderly group will only grow in the future because of the ageing of the population. It is crucial to treat depressive and anxiety symptoms, because they are the most important predictors of developing a full-blown depressive or anxiety disorder. However, the evidence for preventive interventions has received little attention in the field of low vision. This study aims to investigate an indicated preventive intervention to prevent the onset of depressive and anxiety disorders in patients who show early signs of the disorders.

Strengths

This study is innovative because the (cost-)effectiveness of a stepped care programme to prevent depression and anxiety has never been tested in a visually impaired population before. Additionally, the programme is based on a successful stepped care intervention for older adults in the general population and other effective components of preventive interventions in the field of low vision. Another strength of this study is that the treatment is aimed at preventing both depression and anxiety. The few studies, that investigated interventions to reduce depression in the field of low vision, did not take anxiety into account while several other studies suggest that anxiety is as important a problem for visually impaired older adults as depression is.[48,49] Moreover, this stepped care programme is embedded within low vision rehabilitation organisations, where healthcare providers with the specific expertise of working with visually impaired older adults can offer treatment to reduce symptoms of depression and anxiety in addition to usual visual rehabilitation care. It is very important to address depression and anxiety in this setting because depression and anxiety seriously complicate successful rehabilitation. By letting healthcare workers from the rehabilitation organisations provide the treatment themselves, continuation of the intervention

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after the end of this trial is highly improved. This pragmatic design enhances the generalisability of this study.

Challenges

The recruitment of participants is likely to be difficult because it is a challenging subject for a very frail population. To address this challenge and to allow patients to receive oral information about the study, all patients (approximately *n*=3,000) who receive written patient information on the study are approached by telephone by the rehabilitation organisations. Still, drop-out rates may be high because of the vulnerability of the population (sickness, death) and because of the quantity and types of questions that are asked. The way in which these questions are asked may be confronting and cause feelings of sadness or worry. Patients might also have low motivation to comply to the different steps of the programme, because of their depressive state.[50] Therapist support will be used to stimulate their motivation.[35] Another challenge is the possibility of contamination: healthcare workers might give more attention to problems of depression and anxiety because of their newly learned skills to provide support for these problems to patients outside the intervention group. Therefore, it is stressed to healthcare workers to not offer treatment according to the stepped care programme to patients outside the intervention group. Finally, it may be difficult to weigh the specific contributions of the various steps in the stepped care programme, because of the pragmatic design of the study. Not all patients of the intervention group follow the same steps of the programme.

Conclusion

The importance and strengths of this study outweigh the challenges. The development and research of the cost-effectiveness of a stepped care programme to prevent depressive and anxiety disorders in visually impaired older adults is of the greatest importance.

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