Economic evaluation of an e-mental health intervention for patients with retinal exudative diseases (E-PsEYE) who receive intra-ocular anti-VEGF injections: RCT

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To evaluate whether the e-mental health intervention E-PsEYE is cost-effective in comparison with usual care from a healthcare and societal perspective in reducing depression and anxiety in patients with retinal exudative diseases. In addition, a...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON45657

Source
ToetsingOnline

Brief title
E-PsEYE RCT

Condition

- Other condition
- Retina, choroid and vitreous haemorrhages and vascular disorders
- Mood disorders and disturbances NEC

Synonym
diabetic retinopathy, down (depression), fear, fright (anxiety), low spirits, macular degeneration, retinal diseases

Health condition

angstsymptomen

Research involving
Human

Sponsors and support

Primary sponsor: Oogheelkunde
Source(s) of monetary or material Support: ZonMW Doelmatigheid

Intervention

Keyword: anxiety, depression, e-mental health, vision impairment

Outcome measures

Primary outcome

Main outcome measures are: depression (measured with the Patient Health Questionnaire-9), and anxiety (measured with the Hospital Anxiety and Depression Scale * Anxiety). Quality-adjusted life-years are determined with the Health Utility Index-3 and the EuroQol-5 Dimensions..

Secondary outcome

Secondary clinical outcomes: adaptation to vision loss (measured with the Adaptation to Vision Loss scale), illness-cognitions related to helplessness, acceptation and disease benefits (measured with the Illness Cognition Questionnaire), vision-related quality of life (measured with the Low Vision Quality of Life questionnaire), mastery (measured with the Pearlin Mastery Scale) and cognitive therapy skills (measured with the Competencies of Cognitive Therapy Scale-Self Report).

Cost-evaluation outcomes: the iMTA Medical Consumption Questionnaire is used to measure health care utilisation and the iMTA Productivity Cost Questionnaire to measure and value absence and presenteeism from paid and unpaid work.

Process evaluation outcomes: compliance (measured with one question on a 10-point scale), patients are asked to keep a diary on how often and for how long they used the intervention, recall of the previous module (measured with one question on a 10-point scale) and patient satisfaction (measured with the Dutch Mental Healthcare thermometer of satisfaction).

A topic list for the semi-structured interviews will be used based on the framework of Fleuren et al. 2004.

Study description

Background summary

Retinal diseases are the leading cause of vision loss in older adults. A drug inhibiting the growth factor VEGF (vascular endothelial growth factor) that is injected into the eye (intravitreal injection) at various intervals can have a beneficial effect. In many cases this can prevent a deterioration of sight. However, the effects vary strongly between patients. The process to progressive vision loss and uncertainty surrounding the effects of the anti-VEGF injections can greatly affect the psychosocial wellbeing of patients. Previous research shows that about one in three patients experience mild symptoms of depression and/or anxiety. These symptoms can have a negative influence on quality of life and may deteriorate the visual and physical condition of people. To guide people in dealing with these symptoms, a self-help course based on cognitive behavioral therapy is offered via the Internet. This intervention requires relatively little effort from professionals, it stimulates patient empowerment and may result in cost savings.

Study objective

To evaluate whether the e-mental health intervention E-PsEYE is cost-effective in comparison with usual care from a healthcare and societal perspective in reducing depression and anxiety in patients with retinal exudative diseases. In addition, a problem analysis for the implementation of E-PsEYE will be performed.

Study design

Single-blinded multicentre randomised controlled trial (n=174) in two parallel groups.
In addition, a qualitative study based on semi structured interviews will be performed with patients (n*8, of whom half also participates in the RCT) who received the E-PsEYE intervention and professionals (n*24) to determine barriers and facilitators of implementation.

Intervention

E-PsEYE is a cognitive behavioural therapy-based e-mental health intervention containing 9 modules aimed at reducing depression and anxiety. A stepped-care service delivery model is used containing three steps: (1) offering the first module, i.e., providing information about anti-VEGF treatment and psycho-education, (2) only offering the 8 follow-up modules when symptoms of depression/anxiety persist after the first module, and 3) referring patients to their general practitioner when symptoms still persist after step 2. E-PsEYE will be delivered on top of usual care.

Study burden and risks

Participating in this study is with minimally exceeding negligible risk. We expect that the burden of E-PsEYE will be acceptable. The focus is on helping patients with symptoms of depression, anxiety, and difficulty in adaptation to vision loss. However, it is possible that the intervention will cause 'adverse effects', causing the symptoms to worsen. In that case the general practitioner is immediately contacted. Moreover, participation is voluntary and participants may drop-out at any time.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria for patients are: (A) patients should have at least mild symptoms of depression and/or anxiety (score of 5 or higher on the Patient Health Questionnaire (PHQ)-9, and/or score of 3 or higher on the Hospital Anxiety and Depression Scale * Anxiety (HADS-A)); (B) patients should be able to speak the Dutch language adequately; and (C) patients should have access to the Internet.;For the problem analysis of the implementation study, social workers who are currently working at low vision rehabilitation organisations (n*8), managers/directors from these organisations (n*2), ophthalmologists (n*4), nurses and desk assistants (n*4), managers/department heads from the Ophthalmology department of Dutch academic and general hospitals (n*3) and health insurers (n*3) will be included. The aim is to involve a diverse group of these professionals (with different backgrounds and demographic characteristics) in order to obtain the best possible picture of barriers and facilitators for the implementation of E-PsEYE.

Exclusion criteria

Exclusion criteria for patients are: (A) patients are cognitively impaired, which is assessed by telephone with the six-item Mini Mental State Examination (score <3); (B) patients have severe depression (score of 20 or higher on the PHQ-9); (C) patients are suicidal; and (D) patients are heavy drinkers (score of 8 or higher on the Alcohol Use Disorders Identification Test questionnaire (AUDIT)).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-08-2017
Enrollment:	202
Type:	Actual

Medical products/devices used

Generic name:	E-PsEYE
Registration:	No

Ethics review

Approved WMO Date:	17-02-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-08-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-01-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	15-03-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL59656.029.16