E-mental health intervention for patients with exudative retinal diseases who receive intraocular anti-VEGF injections (E-PsEYE) - pilot study

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To investigate if E-PsEYE leads to a reduction in depression and anxiety symptoms (primary outcomes) and problems with adaptation to vision loss(secondary outcome). Conducting a process evaluation to determine adherence and patient satisfaction. To...

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

Summary

ID

NL-OMON43082

Source
ToetsingOnline

Brief title
E-PsEYE pilot

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: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Soma_Psyche VUmc

Intervention

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

Outcome measures

Primary outcome

Depression symptomatology is measured with the PHQ-9 questionnaire (containing 9 questions on a 4-point Likert scale, with total scores ranging from 0 to 27, with higher scores indicating higher symptoms of depression). Anxiety symptomatology is measured with the HADS-A questionnaire (containing 7 questions on a 4-point Likert scale, with total scores ranging from 0 to 21, with higher scores indicating more anxiety symptoms). Both questionnaires are widely used and validated in a visually impaired sample.

Secondary outcome

Adaptation to vision loss is measured with the Adaptation to Vision Loss (AVL) scale (with nine questions on a 4-point Likert scale, with total scores ranging from 0 to 27, with higher scores indicating better acceptance). Compliance is operationalized by patients rating their effort and social workers rating patients* compliance to the intervention, based on a 10-point scale (0=no effort/compliance to 10=full effort/compliance). Patient satisfaction is measured with the Dutch Mental Healthcare (MH) thermometer of satisfaction: a widely used 20-item questionnaire providing information on patients*

satisfaction on provided information, relationship with the social worker, and

results of the treatment.

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 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 (called E-PsEYE) is offered via the Internet. This intervention requires relatively little effort from professionals, it stimulates patient empowerment and may result in cost savings. The purpose of this study is to pilot-test (n=30) this intervention.

Study objective

To investigate if E-PsEYE leads to a reduction in depression and anxiety symptoms (primary outcomes) and problems with adaptation to vision loss(secondary outcome). Conducting a process evaluation to determine adherence and patient satisfaction. To examine the feasibility of the pilot study as a prelude to a randomized controlled trial (RCT) in a larger group of patients to determine the effectiveness of the E-PsEYE intervention. Data from the pilot study can be used to optimize the intervention (increase feasibility), to get an impression of the effect, and to be able to perform a proper sample size calculation.

Study design

Based on a pilot study (n=30), the feasibility of performing an RCT on the cost-effectiveness of E-PsEYE is determined. All outcomes are measured at baseline and after 3 months.

Intervention

E-PsEYE is a cognitive behavioural therapy (CBT)-based e-mental health intervention (offered via the Internet), consisting of nine modules designed to reduce depression and anxiety and increase adaptation to vision loss. The programme consists of a welcome module, in which the patient is informed about his disease and the effects of the anti-VEGF injections and the content of the intervention. Also, information on follow-up care is provided, such as care from low vision rehabilitation organisations. After the welcome module, depression, anxiety and adaptation to vision loss will be determined with a "mood thermometer". If patients have symptoms, 8 follow-up modules will be provided, supported online by a social worker from Royal Dutch Visio (low vision rehabilitation organisation). The 8 modules are based on the previously developed and effective self-help course for visually impaired elderly *Blik op je Dip* are aimed at: 1) dealing with retinal diseases and uncertainty surrounding anti-VEGF injections; 2) dealing with depression and anxiety; 3) dealing with fatigue and stress; 4) participating in pleasurable activities; 5) replacing self-defeating thoughts with healthier thoughts; 6) identifying and replacing negative thought patterns; 7) identifying and replacing negative communication styles; and 8) setting goals for the future. The duration of the intervention depend on the needs of patients, but takes a maximum of 3 months.

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 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.

Exclusion criteria

Exclusion criteria are: (A) patients are cognitively impaired, which is assessed by telephone with the six-item Mini Mental State Examination (score <3); and (B) patients have severe depression (score of 20 or higher on the Patient Health Questionnaire (PHQ)-9).

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-10-2016
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	18-10-2016
Application type:	First submission
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	NL58660.029.16