E-mental health treatment for patients with eye diseases (E-PsEYE): RCT

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19919

Source
NTR

Brief title
E-PsEYE RCT

Health condition

E-mental health
Depression
Anxiety
Eye diseases
Economic evaluation

Sponsors and support

Primary sponsor: VU University Medical Centre
Source(s) of monetary or material Support: ZonMw Doelmatigheid

Intervention

Outcome measures

Primary outcome

Main outcome measures are:

(1) depression (Patient Health Questionnaire-9);

(2) anxiety (Hospital Anxiety and Depression Scale – Anxiety)

(3) quality-adjusted life-years (determined with the Health Utility Index-3 and the Euroqol 5-Dimensions).

Secondary outcome

Secondary clinical outcomes are:

(1) adaptation to vision loss (Adaptation to Vision Loss scale);

(2) illness-cognitions (Illness Cognition Questionnaire);

(3) vision-related quality of life (Low Vision Quality of Life questionnaire);

(4) mastery (Pearlin Mastery Scale);

(5) cognitive therapy skills (Competencies of Cognitive Therapy Scale-Self Report).

Cost-evaluation outcomes are:

(1) health care utilisation (iMTA Medical Consumption Questionnaire);

(2) absence and presenteeism from work (iMTA Productivity Cost Questionnaire).

Process evaluation outcomes are:

(1) compliance;

(2) recall;

(3) patient satisfaction (Dutch Mental Healthcare thermometer);

(4) therapist satisfaction.

During the trial, a qualitative problem analysis study on barriers and facilitators for implementation will be conducted to identify and target barriers for nationwide implementation.

Study description

Background summary

Objective: To evaluate whether 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.

Hypothesis: E-PsEYE in comparison with usual care is cost-effective.

Study design: Single-blinded multicentre randomised controlled trial in two parallel groups.

Study Population: Patients aged 50 years or older with retinal exudative diseases, and (at least) mild symptoms of depression and/or anxiety, who receive intra-ocular anti-VEGF injections at one of five participating hospitals.

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 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.
Usual care: Usual care includes care provided by the ophthalmology departments of the five participating hospitals and other healthcare providers.

Outcome measures: Main outcome measures are: depression (measured with the Patient Health Questionnaire-9), anxiety (measured with the Hospital Anxiety and Depression Scale – Anxiety) and quality-adjusted life-years, which is determined with the Health Utility Index-3 and the Eurqol 5-Dimensions.
Sample size: A total of 174 participants will be included in the trial.

Dat analysis: Cost-effectiveness will be based on intention to treat and will be performed from a healthcare and societal perspective. Guidelines by the ISPOR Task Force will be used for the BIA.

Sensitivity analyses will be performed based on different scenarios from the perspective of decision makers.

Study objective

E-PsEYE in comparison with usual care is cost-effective.

Study design

Five measurements take place: at baseline, after 3, 6, 9, and 12 months.

Intervention

E-PsEYE is a patient-centered, cognitive behavioral therapy (CBT)-based e-mental health intervention, offered via the Internet with digital and telephone guidance of a social worker, for patients with retinal exudative diseases who receive anti-VEGF treatment.

It contains 9 modules aimed at: (1) information and psychoeducation; (2) dealing with retinal diseases and uncertainty surrounding treatment; (3) dealing with depression and anxiety; (4) dealing with fatigue and stress; (5) participating in pleasurable activities; (6) replacing self-defeating thoughts with healthier thoughts; (7) identifying and replacing negative thought patterns; (8) identifying and replacing negative communication styles; and (9) setting goals for the future.

A stepped-care model with three steps will be used to deliver the intervention: (1) offering the first module, i.e. providing information and psycho-education, (2) only offering the 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 two.

If required, an ICT-trainer will provide a computer training before participants start using the intervention.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, patients must meet all of the following criteria:

(1) they should be 50 years or older;

(2) they should be diagnosed with a retinal disease (i.e. macular degeneration, diabetes retinopathy and/or macula oedema);

(3) they should be treated with anti-VEGF injections for their retinal disease;

(4) they should have at least mild symptoms of depression and/or anxiety (score of 5 or higher on the Patient Health Questionnaire-9, and/or score of 3 or higher on the Hospital Anxiety and Depression Scale – Anxiety);

(5) they should be able to speak the Dutch language adequately;

(6) they should have access to the Internet.

Exclusion criteria

Patients are excluded from participation in this study when:

(1) they are cognitively impaired, which is assessed by telephone with a score < 3 on the six-item Mini Mental State Examination;

(2) have a score of 20 or higher on the Patient Health Questionnaire-9, indicating severe symptoms of depression;

(3) indicate to be suicidal;

(4) are heavy drinkers (score of 8 or higher on the Alcohol Use Disorders Identification Test).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-06-2017
Enrollment:	174
Type:	Unknown

Ethics review

Positive opinion

Date:	13-04-2017
Application type:	First submission

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
NTR-new	NL6182
NTR-old	NTR6337
Other	ZonMw : 80-84300-98-71046

Study results

Summary results
A study protocol article will be published and two peer reviewed publications will be published:
(1) cost-effectiveness of E-PsEYE, including process-evaluation;
(2) implementation study.