

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

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

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON19919

Bron

Nationaal Trial Register

Verkorte titel

E-PsEYE RCT

Aandoening

E-mental health
Depression
Anxiety
Eye diseases
Economic evaluation

Ondersteuning

Primaire sponsor: VU University Medical Centre

Overige ondersteuning: ZonMw Doelmatigheid

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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 Euroqol 5-Dimensions.

Sample size: A total of 174 participants will be included in the trial.

Data 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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

De Boelelaan 1117
H.P.A. Aa, van der

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Anders
(Verwachte) startdatum:	01-06-2017
Aantal proefpersonen:	174
Type:	Onbekend

Ethische beoordeling

Positief advies	
Datum:	13-04-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6182
NTR-old	NTR6337
Ander register	ZonMw : 80-84300-98-71046

Resultaten

Samenvatting resultaten

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.