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

Gepubliceerd: 06-09-2016 Laatst bijgewerkt: 18-08-2022

It is feasible to investigate the (cost)effectiveness of E-PsEYE in reducing depression and anxiety symptomatology in a randomized controlled trial (RCT).

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27788

Bron
NTR

Verkorte titel
E-PsEYE pilot

Aandoening

e-mental health; vision impairment; depression; anxiety

Ondersteuning

Primaire sponsor: VU University Medical Centre Amsterdam
Overige ondersteuning: Soma-Psyche VU University Medical Centre and Royal Dutch Visio (low vision rehabilitation centre)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Depression symptomatology is measured with the PHQ-9 questionnaire. Anxiety symptomatology is measured with the HADS-A questionnaire. Both questionnaires are widely

used and validated in a visually impaired sample.

Toelichting onderzoek

Achtergrond van het onderzoek

Retinal exudative diseases are the leading cause of vision loss in older adults. They cause pathologically changed, and newly formed blood vessels to leak and damage the retina, reducing vision. There is no cure for these diseases, but pharmacological inhibition of the vascular endothelial growth factor (VEGF) in the eye can have a beneficial effect. Anti-VEGF drugs are injected into the eye at various intervals. In approximately one third of cases these injections lead to substantial improvement in vision. However, about one third will perceive further vision loss despite treatment, and the effects vary strongly between patients.

The uncertainty of progressive vision loss and the effectiveness of anti-VEGF injections can have a great impact on the psychological well-being of patients. Research shows that approximately one in three patients experience mild symptoms of depression and/or anxiety. These symptoms are the most important predictors of developing a DSM-V depressive or anxiety disorder and can lead to increased vision-specific disability, decreased health-related quality of life, and increased mortality.

To support patients in dealing with these symptoms, a cognitive behavioural therapy (CBT)-based e-mental health intervention was developed. This intervention is expected to be cost-effective, since it is accessible (i.e., patients can use it at home), patient empowerment is stimulated, and relatively little effort from professionals is needed.

The aim of this pilot study is to examine the feasibility of E-PsEYE in a pilot study as a prelude to performing a randomized controlled trial (RCT).

Doel van het onderzoek

It is feasible to investigate the (cost)effectiveness of E-PsEYE in reducing depression and anxiety symptomatology in a randomized controlled trial (RCT).

Onderzoeksopzet

All outcomes are measured at baseline and after 3 months by means of written questionnaires (before and after study).

Onderzoeksproduct en/of interventie

A cognitive behavioural therapy-based e-mental health intervention (offered via the Internet) will be investigated, consisting of nine modules designed to reduce depression and anxiety and increase adaptation to vision loss.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in the pilot study: (1) 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)), (2) patients should be able to speak the Dutch language adequately, (3) patients should have access to the Internet, and (4) patients should be provide written informed consent to participate.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

Patients are excluded from participation when: (1) they are cognitively impaired, which is assessed with a score <3 on the six-item Mini Mental State Examination (MMSE), (2) patients have a score of 20 or higher on PHQ-9, indicating severe symptoms of depression. These patients will be referred to their general practitioner to discuss other (more intensive) treatment options.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2016
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-09-2016
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	NL5894
NTR-old	NTR6082
Ander register	: 2002829 VUmc/EMGO+

Resultaten