E-nergEYEze, a vision-specific eHealth intervention based on cognitive behavioral therapy and self-management to reduce fatigue in adults with visual impairment

Published: 28-05-2019
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The aim is to describe the study protocol of a randomized controlled trial testing E-nergEYEze.

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

Summary

ID

NL-OMON28085

Source
NTR

Brief title
E-nergEYEze

Condition

- Vision disorders

Synonym
Fatigue, Visual impairment, Cognitive behavioral therapy, Self-management, eHealth, Randomized controlled trial

Health condition
People with a visual impairment and in the experience of severe fatigue

Research involving

Human

Sponsors and support

Primary sponsor: Amsterdam University Medical Centres
Source(s) of monetary or material Support: ZonMw

Intervention

- Psychosocial intervention

Explanation

Outcome measures

Primary outcome

Fatigue severity will be measured with the Fatigue Severity (FS) subscale of the Checklist Individual Strenghts (CIS)

Secondary outcome

Adaptation to vision loss, symptoms of depression, anxiety, vision-related quality of life, work functioning and work participation, need for recovery, sleep disorder, health care utilisation, medication use, absenteeism and presenteeism from paid and unpaid work, health-related quality of life.

Study description

Background summary
More than half of the adults with visual impairment experience severe symptoms of fatigue, with a

negative impact on daily life. Since there is no evidence-based treatment to reduce fatigue in adults with visual impairment, we developed E-nergEYEze, an eHealth intervention based on cognitive behavioral therapy and selfmanagement tailored to the needs of visually impaired adults.

Study objective
The aim is to describe the study protocol of a randomized controlled trial testing E-nergEYEze.

Study design
A randomized controlled trial will be conducted to investigate the cost-effectiveness and cost-utility of EnergEYEze to reduce fatigue severity compared to care as usual from a

healthcare and societal perspective. A total of 172 severely fatigued adults with visual impairment will be recruited and randomized to either the E-nergEYEze intervention plus care as usual or to care as usual only (ratio 1:1). Inclusion criteria are having a visual impairment, experiencing severe fatigue (Checklist Individual Strength – subscale Fatigue Severity: CIS-FS > 35), being 18 years or older, understanding the Dutch language, and having access to the internet. The intervention consists of one face-to-

face session and a computer training followed by internet-based modules with information and assignments on coping with fatigue. During this 5-month intervention, participants will be digitally supported by a social worker. All measurements will be administered at baseline, after 6 and 12 months, and additionally, those related to costeffectiveness at 3 and 9 months. The primary outcome is fatigue severity (CIS-FS).

Intervention
eHealth intervention

Contacts

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Eligibility criteria

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

Inclusion criteria

➤Being visually impaired according to WHO criteria of any

cause (ophthalmic disorder)

➤ Being 18 years or older

➤ Understanding of the Dutch language

➤ Experiencing severe fatigue (CIS-FSa-score > 35) [30]

➤ Having access to the internet

Exclusion criteria

➤ Experiencing severe cognitive limitations assessed with the 6-item screener (short validated MMSEb)

➤ Currently receiving treatment, or having received treatment in the last 12 months by a medical specialist for a comorbid disease that clearly is the main cause of fatigue (MS, cancer, psychiatric disorder).

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Single
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-10-2020
Enrollment:	172
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Approved WMO Date:	09-08-2019
Application type:	First submission
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 52602
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7764
CCMO	NL67802.029.18
OMON	NL-OMON52602

Study results