Reducing fatigue in visually impaired adults with E-nergEYEze: An RCT to assess the cost-effectiveness of a blended vision-specific E-health based cognitive behavioral & self-management intervention.

Published: 09-08-2019
Last updated: 15-05-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52602

Source
ToetsingOnline

Brief title
E-nergEYEze

Condition

- Other condition
- Vision disorders

Synonym
(fatigue,) sight loss, heaviness, overtiredness, visual disability (visually impaired)

Health condition

Vermoeidheid

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMw InZicht

Intervention

Keyword: E-mental health, Fatigue, RCT, Vision impairment

Outcome measures

Primary outcome

The intervention and control group will both answer questionnaires by telephone to obtain research data. These interviews are conducted by blinded research assistants at baseline (T0), 6 months (T2) and 12 months (T4).

The primary outcome measure is: severity of fatigue (Checklist Individual Strengths-Fatigue Scale).

Secondary outcome

Usability study:

Use will be made of thinking aloud, semi-structured interviews, observation and video recordings to assess usability.

RCT:

The secondary outcome measured are: impact of fatigue (measured with the Modified Fatigue Impact Scale; Adaptation to vision loss-9), depression

(measured with thePatient Health Questionnaire-9 (depression), Anxiety (measured with the Hospital Anxiety Depression scale - Anxiety subscale), impact of vusial impairment (measured with the Impact of Visual Impairment questionnaire, IVI), work functioning (measured with the Work Functioning Questionnaire-2.0), need for recovery (measured with the Need for Recovery questionnaire), trouble sleeping (measured with the Holland Sleep Disorders Questionnaire), health care utilisation (measured with the Health care utilisation and medication use (iMTA Medical Costs Questionnaire), absence and presenteeism from paid and unpaid work (measured with the Absenteeism and presenteeism (iMTA Productivity Cost Questionnaire), and quality-adjusted life years are determined with the Euroqol 5 Dimensions 5 levels.

Process evaluation (i.a. feasibility study):
Cognitive therapy skills are measured with the Competencies of Cognitive Therapy Scale-Self Report (CCTS-SR) of which two versions will be used: a patient and a therapist version. Compliance is measured by patients rating their effort and social workers rating patients* compliance to the E-nergEYEze intervention, based on a 10-point scale. The intervention platform Minddistrict logs how often and for how long they used the intervention. Recall is measured by social workers rating the degree to which patients seem to remember last modules on a 10-point scale. Patient satisfaction with the intervention is measured with the Dutch Mental Healthcare (MH) thermometer of satisfaction. Therapist satisfaction and adherence is measured by means of evaluation forms filled out by social workers during the intervention.

Working mechanism:

The 7-item Brief Illness Perceptions Questionnaire is used to assess perceptions and beliefs about fatigue, the Self-efficacy scale to assess how fatigue is handled and the Fatigue Catastrophizing Scale to assess negative cognitions towards fatigue in addition the Adaption to vision loss (AVL)and PHQ, and the CCTS-SR, but also patient characteristics such as severity of vision loss (blind or partially sighted) and visual field loss, eye condition, stable vs progressive eye disease, living alone or with others, work participation, financial situation.

Study description

Background summary

Results from our former study show that 57% of visually impaired adults have severe symptoms of fatigue, which is at least twice as high as in the general Dutch population. Having disabling fatigue in addition to visual impairment, is associated with incremental societal costs that largely determine the economic burden of low vision through increased healthcare utilization and reduced work participation. Previous research showed that e.g. accommodative coping strategies, depressive symptoms, the cognitive effort needed for visual perception and hindrance of light are associated with fatigue in people with visual impairment. Unlike for some other chronic diseases, effective treatment options for fatigue have not been developed for the visually impaired. Although clients have indicated that reducing fatigue is a rehabilitation goal of high importance, professionals from Dutch rehabilitation services have acknowledged this to be a major gap in their knowledge, skills and treatment options.

Study objective

The objective of the study is to develop and test a blended vision-specific E-health-based cognitive behavioral & self-management intervention (*E-nergEYEze*). Our specific goals are: (1) to further develop E-nergEYEze for visually impaired adults; (2) investigate its usability and feasibility; (3) study the effectiveness of E-nergEYEze compared with care as usual in a randomized controlled trial in reducing fatigue severity; (4) investigate

cost-effectiveness and cost-utility from a healthcare and societal perspective; (5) investigate fidelity and intervention uptake with a process evaluation; (6) the working mechanisms ,which might be the psychological mechanisms, such as self-efficacy, illness perceptions and beliefs and negative cognitions towards fatigue that might explain whether the intervention is effective in subgroups of patients with a structural equation model and (7) to Investigate the association between cognitive overload and fatigue based on screening data and what factors confound or mediate this association (i.e. motivation, activity, demographic and disease specific characteristics).

Study design

After the blended self-management intervention has been tested in a usability (N=5) and feasibility study (N=10) to ensure applicability and to increase implementation chances, a pragmatic single blinded randomized controlled trial (N=172) will be performed, stratified by the rehabilitation service region and employment status.

Intervention

The blueprint of E-nergEYEze contains an introduction module plus eight thematic modules: (a) understanding vision-related fatigue; (b) experiencing visual impairment and coping; (c) helping, fatigue reducing thoughts; (d) distribute and build up activities; (e) communication and social support; (f) stress and relaxing; (g) optional: improving sleep; (h) optional: work optimization; (i) the future. E-nergEYEze is guided by social workers via a one-hour face-to-face start session, digital (appr. 3 hrs) and telephone contacts (2 times appr. 30-60 min), with a one-hour specific professional computer training. The intervention takes five months and E-nergEYEze will be compared to care as usual, which is any care a patient needs from the low vision services or other care services.

Study burden and risks

Participating in this study is with minimally exceeding negligible risk. We expect that the burden of E-nergEYEze will be acceptable. The focus is on helping patients with symptoms of fatigue in adaption to vision impairment. However, it is possible that the intervention will cause 'advers effects', causing the symptoms to worsen. In that case the general practitioner is immediately contracted. 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

Inclusion criteria

Inclusion criteria:
- visually impaired according to WHO criteria + guidelines of rehabilitation center, of any cause (eye condition); moderate visual impairment or worse and, in consultation with the research team, a progressive mild visual impairment.
- 18 years or older
- understanding of the Dutch language
- experiencing severe fatigue (CIS-score>35)
- having home access to internet

Exclusion criteria

Exclusion criteria:
- severe cognitive limitations assessed with the 6-item screener (short validated Mini Mental State Examination).

- currently receiving treatment, or having received treatment in the last 12 months for comorbid disease that clearly is the main cause of fatigue (e.g. MS, cancer, psychiatric disorder).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-10-2019
Enrollment:	187
Type:	Actual

Medical products/devices used

Generic name:	E-nergEYEze
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	09-08-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-09-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	26-09-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-06-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-09-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-02-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-12-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-12-2022
Application type:	Amendment
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

ID: 28085
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL67802.029.18
OMON	NL-OMON28085