Stepped-care to reduce depression and anxiety in visually impaired older adults - a randomised controlled trial.

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

Summary

ID

NL-OMON39321

Source
ToetsingOnline

Brief title
Stepped-care RCT

Condition

- Other condition
- Vision disorders
- Mood disorders and disturbances NEC

Synonym
down (depression), fear, fright (anxiety), low spirits, vision loss, visual disability (visual impairment)

Health condition

angststoornissen en symptomen

Research involving
Human

Sponsors and support

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

Intervention

Keyword: anxiety, depression, stepped-care, visual impairment

Outcome measures

Primary outcome

The main study parameter is the cumulative incidence of DSM-IV major depressive or anxiety disorder after 24 months as measured using the Mini International Neuropsychiatric Interview.

Secondary outcome

Secundary dependent variables are:

- Subthreshold depression and/or anxiety symptoms.

- Vision and health-related quality of life and adaptation to vision loss.

- Process-evaluation outcomes.

- Cost measurement and valuation.

Secundary independent variables are:

- Socio-demographic and disease variables (age, gender, education, cognitive functioning, co-morbidity, care and low vision aids received in the past half year of the rehabilitation centres etc.).

Study description

Background summary

In our previous study we found that one out of three visually impaired older adults experience significant depression and/or anxiety symptoms. The percentage is in concordance with international studies (22-42%) and is at least two times the amount found in general populations (10-15%). Health care utilisation is elevated in populations with subclinical levels of depression and anxiety and quality of life is seriously affected. Depressive and anxiety symptoms may influence factors that are necessary for a successful rehabilitation, such as the ability to learn new tasks, processing information and being oriented towards achieving certain goals. Furthermore, these symptoms are the most important predictors of developing a depressive or anxiety disorder according to DSM-IV criteria. It is therefore crucial to treat these symptoms.

Study objective

The goal of this study is to develop and investigate the effectiveness and cost-effectiveness of a stepped-care programme for visually impaired older adults to diminish subthreshold depression and/or anxiety symptoms and to prevent a full depressive or anxiety disorder form occurring.

Study design

Using a multi-center international randomized controlled trial a stepped-care programme will be developed and tested.

Intervention

The participants will be randomly assigned to a treatment (stepped-care program) or a control group (usual care). The stepped-care programme consists of four steps which each last 3 months. Participants will sequentially receive a watchfull waiting approach, a cognitive behaviour therapy*based bibliotherapy, brief cognitive behaviour therapy * based problem-solving treatment (PST) and referral to professional treatment elsewhere, if required. The intervention is developed and implemented in two Dutch and one Belgian rehabilitation centre for the visually impaired.

Study burden and risks

Participation to this study is minimally exceeding negligible risk. We expect that the burden of the stepped-care programme will be acceptable. In the stepped-care programme the focus is on helping clients with subthreshold

depression and anxiety, which may prevent the development of psychiatric disorders in many cases. However, it is possible that because of the treatment so-called 'adverse effects' can occur, causing the symptoms to worsen. In that case the general practitioner is immediately contacted. Participation is always voluntary and participants may drop-out at any time. The control group receives usual care by the rehabilitation centres and they are allowed to utilize any additional care they need.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Informed consent of the participants
- Participants must be visually impaired and entered one of the three low vision rehabilitation centres.

- Participants must be 50 years or older.
- Participants must be able to speak Dutch.
- Participants must have subthreshold depression and/or anxiety, measured with a CES-D and HADS-A score.

Exclusion criteria

- Participants with severely impaired cognitive functioning will be excluded. This will be detected with the 'six-item screener' (a short version of the MMSE) at baseline.
- Participants with a DSM-IV psychiatric disorder will be excluded. This will be measured by the Mini (Mini International Neuropsychiatric Interview).
- Psychotic or suicidal participants.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-09-2012
Enrollment:	198
Type:	Actual

Ethics review

Approved WMO

Date:	14-09-2012

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-02-2014
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

No registrations found.

In other registers

Register	ID
CCMO	NL39789.029.12

Study results

Date completed:	01-01-2016
Actual enrolment:	235

Summary results
Trial is onging in other countries