Treatment for depression and anxiety in visually impaired older adults.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22928

Source
NTR

Brief title
Stepped-care RCT

Health condition

- Visual impairment (visuele beperking)
- Depression (depressie)
- Anxiety (angst)

Sponsors and support

Primary sponsor: VU University Medical Center
Source(s) of monetary or material Support: ZonMw

Intervention

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:

1. Subthreshold depression and/or anxiety symptoms;

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

3. Process-evaluation outcomes;

4. Cost measurement and valuation.

Secundary independent variables are:

1. 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

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. A multi-center international randomised controlled trial in 2 parallel groups will be used. A total of 230 participants will be randomly assigned to a treatment (stepped-care programme) or a control group (usual care). The intervention is developed and implemented in two Dutch and one Belgian rehabilitation centre for the visually impaired.

Study objective

A stepped-care program, developed for visually impaired elderly with subtreshold depression and/or anxiety, in cooperation with psychologists and social workers of three rehabilitation centres, will prevent the development of a full depressive or anxiety disorderor from occuring or diminish subclinical levels.

Study design

TIME FRAME:

DEVELOPMENT OF THE INTERVENTION: “STEPPED-CARE PROGRAMME” (JAN-SEP 2012):

1. Send study protocol to Medical Ethics Committee and other formal procedures (Jan 2012);

2. Literature study, study of existing stepped-care programmes in Amsterdam and Cardiff, including a possible visit to Cardiff University (Jan-May 2012);

3. Focus group with professionals to develop stepped-care (psychologists and social workers) (Mar/Apr 2012);

4. Focus group with patient representatives to further refine stepped-care (May 2012);

5. Stepped-care programme ready (Jun 2012);

6. Start first wave including patients into the trial (Jul 2012);

7. Writing first publication (Aug-Dec 2012).

RANDOMISED CONTROLLED TRIAL: (SEP 2012 – FEB 2014):

1. Training of occupational therapists to deliver the self-help course (Oct 2012);

2. Training of psychologists and social workers to deliver PST (Jan 2013);

3. Second wave including patients into the RCT (Jan 2013);

4. Participants in intervention group follow stepped-care programme in two waves (Sep 2012 – Aug 2013 and Mar 2013 – Feb 2014).

MEASUREMENTS (SEP 2012 – AUG 2015):

1. Intervention until Feb 2014;

2. Measurements until Feb 2015 (= last measurement - 24-month after baseline - of second wave participants);

3. In between measurements, publications 2-5 are prepared (introduction and method sections) and the General Introduction of the thesis is written.

PUBLICATION (JAN 2014 – DEC 2015):

1. Preparing statistical analyses primary and secondary outcomes and cost-effectiveness study (Jan-Jul 2014);

2. Writing publication (2) “short term outcomes” (Aug-Nov 2014);

3. Final long-term outcome analyses after Feb 2015;

4. Preparing publication (3) “long term primary outcomes” (Dec 2014-Mar 2015);

5. Preparing publication (4) “secondary outcomes and process evaluation” (Apr-Jun 2015);

6. Preparing publication (5) “cost-effectiveness of stepped-care” (Jul-Sep 2015);

7. Finishing publications and General Discussion thesis (Oct-Dec 2015).

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:

1. A watchful waiting approach to see if symptoms spontaneously disappear;

2. A cognitive behaviour therapy–based bibliotherapy. Participants will receive a telephone call by a trained occupational therapist to explain the second step programme and to make an appointment for a home visit. During the visit, information about mild depression and anxiety and simple advice on how to cope with these symptoms is given (this visit will approximately take 45 minutes). During a subsequent visit an audio self-help course will be offered (this will also take approximately 45 minutes). If necessary the occupational therapist may pay another visit or conduct telephone calls to encourage participants to continue with the course;

3. Brief cognitive behaviour therapy – based problem-solving treatment (PST). Again, participants will receive information about the intervention by telephone. If the participant agrees, a trained psychologist or social worker makes a first appointment at the participant's home or, if possible, at the rehabilitation centre. PST consists of a maximum of 7 sessions, during which the stages of problem solving are explained and then applied to problems encountered in daily life. (The first session will take approximately 1 hour, the following sessions will take approximately 45 minutes);

4. The last step is 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.

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Eligibility criteria

Inclusion criteria

1. Informed consent of the participants;

2. Participants must be visually impaired and entered one of the three low vision rehabilitation centres;

3. Participants must be 50 years or older;

4. Participants must be able to speak Dutch;

5. Participants must have subthreshold depression and/or anxiety, measured with a CES-D score (Center for Epidemiologic Studies Depression) and the HADS-A (Hospital Anxiety and Depression scale section A).

Exclusion criteria

1. Participants with severely impaired cognitive functioning, which will be detected with the 'six-item screener' (a shortened version of the MMSE (Mini-mental state examination) at baseline;

2. Participants with a DSM-IV psychiatric disorder, measured by the Mini (Mini International Neuropsychiatric Interview).

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2012
Enrollment:	230
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-02-2012
Application type:	First submission

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
NTR-new	NL3152
NTR-old	NTR3296
Other	ZonMw : 60-00635-98-108
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A