

# Treatment for depression and anxiety in visually impaired older adults.

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

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving nog niet gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON22928

### Bron

NTR

### Verkorte titel

Stepped-care RCT

### Aandoening

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

## Ondersteuning

**Primaire sponsor:** VU University Medical Center

**Overige ondersteuning:** ZonMw

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

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.

## **Toelichting onderzoek**

### **Achtergrond van het onderzoek**

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 from 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.

### **Doel van het onderzoek**

A stepped-care program, developed for visually impaired elderly with subthreshold 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 disorder or from occurring or diminish subclinical levels.

### **Onderzoeksopzet**

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).

## Onderzoeksproduct en/of interventie

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.

## Contactpersonen

### Publiek

De Boelelaan 1117  
H.P.A. Aa, van der  
Amsterdam 1081 HZ  
The Netherlands  
+31 (0)20 4445064

## Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

## Onderzoekopzet

## Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Geneesmiddel

## Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2012
Aantal proefpersonen:	230
Type:	Verwachte startdatum

## Ethische beoordeling

Positief advies	
Datum:	13-02-2012
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	NL3152

**Register**

NTR-old

Ander register

ISRCTN

**ID**

NTR3296

ZonMw : 60-00635-98-108

ISRCTN wordt niet meer aangevraagd.

## Resultaten

**Samenvatting resultaten**

N/A