# Prevention of anxiety and depression in the elderly

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>		
20/12/2005	No longer recruiting	☐ Protocol		
Registration date 20/12/2005	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
30/03/2011	Mental and Behavioural Disorders			

#### Plain English summary of protocol

Not provided at time of registration

# Contact information

#### Type(s)

Scientific

#### Contact name

Dr P.J. van 't Veer-Tazelaar

#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

**NTR418** 

# Study information

#### Scientific Title

A study to test the feasibility and effects of a generic stepped care approach for community elderly with symptoms of subtreshold anxiety and/or depression

#### Acronym

PIKO-D

#### **Study objectives**

The stepped care approach will lead to a significantly reduced incidence of clinical anxiety and depression in two years and will reduce symptoms level compared to usual care.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

The design and conduct of the study was approved by the Ethics Committee of Vrije University Medical Centre, Amsterdam.

#### Study design

Multicentre, randomised, single blind, active controlled, parallel group trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

# Study type(s)

Prevention

#### Participant information sheet

# Health condition(s) or problem(s) studied

Anxiety, depression

#### **Interventions**

Stepped care programme:

- 1. Symptom monitoring every three months (CES-D)
- 2. Leaflet and selfhelp book coached by homecare nurse
- 3. Problem solving treatment by community psychiatric nurses (CPN)
- 4. Suggestion to discuss medication with general practitioner (GP)

Control: usual care

# Intervention Type

#### Other

#### Phase

Not Applicable

#### Primary outcome measure

Incidence of clinical anxiety and/or major depression in two years (Mini International Neuropsychiatric Interview [MINI])

#### Secondary outcome measures

- 1. Reduction of self-reported anxiety and/or depressive symptoms as measured with the Center for Epidemiologic Studies Depression Scale (CES-D), the Hospital Anxiety Depression Scale (HADS-A)
- 2. Improvement of quality of life (36-item short form health survey [SF-36])
- 3. Mortality

#### Overall study start date

15/09/2004

#### Completion date

15/09/2007

# **Eligibility**

#### Key inclusion criteria

- 1. Persons 75 years of age and over living in the community
- 2. Centre for Epidemiological Studies Depression (CES-D) score of 16 or higher

## Participant type(s)

Patient

#### Age group

Senior

#### Sex

Both

## Target number of participants

170

## Key exclusion criteria

- 1. Meeting criteria for major depression and/or clinical anxiety
- 2. Insufficient mastery of the Dutch language
- 3. Unwilling or unable to give informed consent

#### Date of first enrolment

15/09/2004

#### Date of final enrolment

15/09/2007

# Locations

#### Countries of recruitment

Netherlands

Study participating centre
EMGO Institute for Research in Extramural Medicine
Amsterdam
Netherlands
1081 HV

# Sponsor information

#### Organisation

Vrije University Medical Centre (VUMC) (Netherlands)

#### Sponsor details

EMGO Institute Van der Boechorststraat 7 Amsterdam Netherlands 1081 BT

#### Sponsor type

University/education

#### Website

http://www.vumc.nl/

#### **ROR**

https://ror.org/00q6h8f30

# Funder(s)

## Funder type

Research organisation

#### **Funder Name**

The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

# **Results and Publications**

## Publication and dissemination plan

Not provided at time of registration

# Intention to publish date

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/07/2006		Yes	No
Results article	results	01/03/2009		Yes	No
Results article	results	01/03/2011		Yes	No