

Prevention of anxiety and depression in the elderly

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 30/03/2011	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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 subthreshold 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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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)

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

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