ISRCTN26474556 https://doi.org/10.1186/ISRCTN26474556

Prevention of anxiety and depression in the elderly

Submission date	Recruitment status
20/12/2005	No longer recruiting
Registration date	**Overall study status**
20/12/2005	Completed
Last Edited	**Condition category**
30/03/2011	Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

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
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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