

PROactive Management Of Depression in the Elderly

Submission date 16/01/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/01/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/03/2012	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym

PROMODE

Study objectives

A screening and stepped care treatment program for elderly with depressive symptoms in general practice will lead to significant reduction of depressive symptoms and costs in comparison to Care As Usual (CAU).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Medical Ethics Committee of the Leiden University Medical Centre (Commissie medische ethiek van het Leids Universitair Medisch Centrum [LUMC]) on the 27th February 2007. We also received a letter of approval from the Raad van Bestuur (Board of Directors) of the LUMC.

Study design

Pragmatic cluster randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Screening

Participant information sheet

Health condition(s) or problem(s) studied

Depressive symptoms

Interventions

In the intervention practices elderly with depressive symptoms will be offered a stepped care treatment program, including:

1. Individual counselling by a community psychiatric nurse
2. Psycho-education by a Coping with Depression group course or a similar therapy on individual basis, and
3. Pharmacological treatment and/or referral for patients with persistence of depressive symptoms after step 1 and 2.

In the control practices elderly will receive care as usual.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Difference in severity of depressive symptoms (Montgomery Asberg Depression Rating Scale [MADRS] baseline - six months).

Secondary outcome measures

Differences (at six and 12 months) in:

1. Percentage responders to treatment
2. Quality of life (Short Form health survey [SF-36], EuroQol questionnaire [EQ-5D])
3. Mortality
4. Use of (in)formal help or home care
5. Medical consumption
6. Cost-effectiveness
7. Costs per Quality Adjusted Life Year (QALY)

Overall study start date

01/03/2007

Completion date

01/03/2009

Eligibility**Key inclusion criteria**

1. Inclusion criteria for screening: elderly aged 75 years and over enlisted in general practices
2. Inclusion criteria for treatment-offer: screen positive for depression (Geriatric Depression Scale [GDS-15] more than four)

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

4000

Key exclusion criteria

1. Exclusion criteria for screening: terminal illness, current treatment for depression, loss of partner/important relative within previous three months

2. Exclusion criteria for treatment-offer: severe cognitive impairment (Mini Mental State Examination [MMSE] less than 19)

Date of first enrolment

01/03/2007

Date of final enrolment

01/03/2009

Locations

Countries of recruitment

Netherlands

Study participating centre

Leiden University Medical Center (LUMC)

Leiden

Netherlands

2300 RC

Sponsor information

Organisation

Leiden University Medical Center (LUMC) (Netherlands)

Sponsor details

Department of Public Health and Primary Care

P.O. Box 9600

Leiden

Netherlands

2300 RC

Sponsor type

Hospital/treatment centre

Website

<http://www.lumc.nl/>

ROR

<https://ror.org/05xvt9f17>

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	01/03/2011		Yes	No
Results article	results	01/07/2012		Yes	No