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PROactive Management Of Depression in the Elderly

Submission date	Recruitment status	[X] Prospectively registered
16/01/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/01/2007	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/03/2012	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr G M van der Weele

Contact details
Leiden University Medical Center (LUMC)
Department of Public Health and Primary Care
P.O. Box 9600
Leiden
Netherlands
2300 RC
+31 (0)71 526 8444
G.M.van_der_Weele@lumc.nl

Additional identifiers

Protocol serial number
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

Study type(s)
Screening

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

Key secondary outcome(s))

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)

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

Healthy volunteers allowed
No

Age group
Senior

Sex
All

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)

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

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