PRoactive Management Of Depression in the Elderly.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28191

Source
NTR

Brief title
PROMODE

Health condition

Depressive symptoms

Sponsors and support

Primary sponsor: Leiden University Medical Center, department of Public Health and Primary Care.
Source(s) of monetary or material Support: ZONMw, programma Doelmatigheid (projectnr 80-007022-98-07502).

Intervention

Outcome measures

Primary outcome

Difference in severity of depressive symptoms (MADRS baseline - 6 months).

Secondary outcome

Differences (at 6 and 12 months) in:
1. Percentage responders to treatment;
2. Quality of life (SF-36, EQ-5D);
3. Mortality;
4. Use of (in)formal help or home care;
5. Medical consumption;
6. Cost-effectiveness;
7. Costs per QALY.

Study description

Background summary

We aim to study the effects and costs of a screening and treatment program for elderly with depressive symptoms in general practice. The design is a pragmatic cluster randomised controlled trial with the general practice as the unit of randomisation.
Elderly aged 75 years and over enlisted in general practices will be screened at baseline for depressive symptoms, measured by the Geriatric Depression Scale (GDS-15). If GDS-15 score is > 4 points intervention or usual care will be offered according to the allocated treatment to their general practice.

Study objective

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 CAU.

Intervention

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.

Contacts

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Eligibility criteria

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 (GDS-15 > 4).

Exclusion criteria

1. Exclusion criteria for screening: terminal illness, current treatment for depression, loss of partner/important relative within previous 3 months;
2. Exclusion criteria for treatment-offer: severe cognitive impairment (MMSE < 19).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2007
Enrollment:	4000
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL822
NTR-old	NTR835
Other	: N/A
ISRCTN	ISRCTN71142851

Study results

Summary results
N/A